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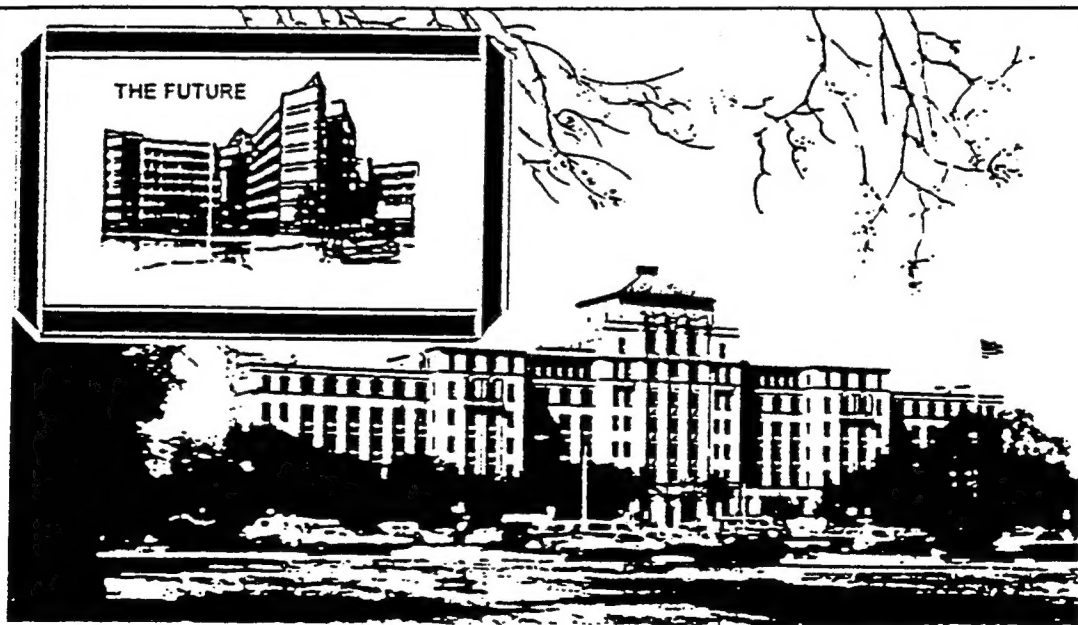


DEPARTMENT OF CLINICAL INVESTIGATION

# ANNUAL RESEARCH PROGRESS REPORT

FISCAL YEAR 1994  
VOLUME I

19950330 037



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BROOKE ARMY MEDICAL CENTER FORT SAM HOUSTON, TEXAS 78234

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## FOREWORD

1994 was another productive year for the Brooke Army Medical Center (BAMC) Department of Clinical Investigation (DCI). The continuing productivity of the DCI is due to the support of the members of the DCI and from the former Commander, BG Russ Zajtchuk; the current Commander, BG Robert L. Claypool; the former Deputy Commander, COL David A. McFarling; the current Deputy Commander, COL William D. Strampel; the former Chief of Staff, COL Douglas A. Barton; the current Chief of Staff, COL Herbert Reamey; and the training program chairmen.


The philosophy of the DCI is to support and encourage the academic pursuits of the housestaff and professional staff. The performance of quality research is only one aspect of this goal. Other aspects are to develop intellectual curiosity and the abilities to design clinical studies, analyze data, interpret results, explain the research efforts in written and oral form, and critically analyze scientific literature. The goal of the DCI is to assist in developing and fostering these research skills in academicians, scientists, and clinicians in the belief that clinical research promotes continuing medical education and ultimately benefits the patient. In keeping with this goal, Drs. Jean Johnson, John Ward, Earl Grant, Curtis Yeager, and James Lamiell have continued to present their package of clinical research instruction to several clinical services.

On 1 September 1994, the new BAMC animal research facility was inspected by the American Association for the Accreditation for Laboratory Animal Care (AAALAC) for accreditation. We received official notification that our facility has received full accreditation for three years. The official results should be forthcoming in the very near future. This was primarily the result of outstanding efforts by our veterinarian, MAJ Carol L. Eisenhower and her staff. The new animal research facility has allowed for substantial increase in the numbers of animal use protocols.

There has been a continuing increase in the acquisition of extramural funding to support the research endeavors of BAMC. The DCI serves as a resource and support service for investigators in obtaining these funds. DCI goals for 1995 will include increasing efforts to obtain extramural funding and broaden the research teaching program to include a discussion of ethics in science and medicine.

This has been a fruitful year for the DCI. MAJ Grant, MAJ Yeager and myself are indebted to the staff of the DCI and BAMC who have supported us during the past year. We are also grateful to those who preceded us and whose efforts made much of the progress of the past year possible. We look forward to another year of service to BAMC.

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JAMES M. LAMIELL  
Colonel, MC  
Chief, Department of Clinical  
Investigation



COMMANDER'S AWARD WINNERS

First Place

Evaluation of a Prototype Double-Lumen  
Multiorificed Catheter for Resuscitating  
Swine from Lethal Air Embolism

Jon A. Hinman  
Captain, Medical Corps  
Anesthesiology and Operative Service  
Department of Surgery

Second Place

Xanthine Oxidase Deficiency Prevents  
Diaphragm Muscle Impairment in Rats  
Exposed to Resistive Breathing

Jackie A. Hayes  
Captain, MC  
Pulmonary Disease/Critical Care Service  
Department of Medicine

Third Place

Functional Sensory Substitution Among  
Diabetics with Lower Extremity  
Peripheral Neuropathy

Steven C. Walker  
Captain, MC  
Transitional Intern

\* \* \* \* \*

## UNIT SUMMARY

### - FISCAL YEAR 1994

#### A. Objectives

The objectives of the Department of Clinical Investigation are as follows:

1. To achieve continuous improvement in the quality of patient care.
2. To assist in the professional growth and development of the house staff by providing guidance and support in clinical research.
3. To provide a milieu conducive to retention of competent staff personnel and recruitment of new personnel.
4. To provide a review body for research proposals by investigators currently assigned to MEDDAC Units in an effort to promote an interest in Army medicine and retention in the Army Medical Corps.
5. To maintain an atmosphere of inquiry consistent with the dynamic nature of the health sciences.
6. To maintain a high professional standard and accreditation of advanced health programs.
7. To assure the highest level of professional standards in the conduct of human research and animal research.

#### B. Technical Approach

All research, investigational and training activities within the Department of Clinical Investigation are conducted under the guidance of AR 40-7, AR 40-3, AR 70-25, AR 70-18, and HSC Reg 40-23. Careful monitoring of all approved protocols is conducted in order to assure strict compliance with the applicable regulations.

#### C. Staffing

<u>Name</u>	<u>Rank</u>	<u>MOS</u>	<u>Title</u>
Lamiell, James M.	COL	61F	Chief
Grant, Earl, Jr.**	MAJ	68C	Biochemist
Yeager, Curtis	MAJ	68A	Microbiologist
Eisenhauer, Carol L.	MAJ	64B	Veterinary Lab Animal Officer
Look, Beatrice M.*	SSG	92B30	NCOIC
Irizarry, Zulma	SGT	92B20	Med Lab Specialist
Guzman, Edwin	SSG	92B30	Med Lab Specialist
White, James	SPC	92B30	Med Lab Specialist
Hunter, Scott	SGT	92B30	Med Lab Specialist

Poff, Jennifer*	SPC	92B10	Med Lab Specialist
Ruiz, Javier	SGT	91T20	Animal Care Specialist
Yoquelet, Curtis	SGT	91T20	Animal Care Specialist
Merrill, Gerald A.	GS11	00401	Research Immunologist
Ayala, Eleanor	GS11	00644	Medical Technologist
Ward, John A.	GS13	00401	Research Physiologist
Johnson, Jean M.	GS12	00610	Research Nurse
Reeb, Barbara	GS11	00644	Medical Technologist
Davey, Inid	GS11	00644	Medical Technologist
(salaried by CHAMPUS- assigned to DCI)			
Trevino, Sylvia	GS11	00644	Medical Technologist
(salaried by CHAMPUS- assigned to DCI)			
Chapa, Isidoro	GS7	00645	Medical Technician
Williams, Dannie	GS7	00404	Biological Lab Technician
Rios, Roberto***	GS9	01020	Med Scientific Illustrator
Smith, Helen J.	GS9	00301	Clin Research Protocol Coord
Aguero, Lynda D.	GS6	01087	Editorial Assistant
Johnson, Maurine E.	GS5	00318	Secretary

\* Assigned May 94, Aug 94

\*\* Reassigned Jun 94

\*\*\* Assigned to IMD with duty in DCI

Personnel:	Authorized	Required	Assigned
Officers -	4	9	4
Civilians -	13	16	13
Enlisted -	8	10	8

#### D. Funding

Type	Fiscal Year 93	Fiscal Year 94
Civilian personnel		
to include benefits	569,368.16	522,776.00
Consumable supplies	163,354.05	152,026.00
Civilian contracts		
to include consultants	4,689.00	4,614.00
TDY	4,883.00	4,279.00
Noninvestment equipment		
(Minor MEDCASE)	-----	-----
Other OMA	-----	-----
OMA Total	718,384.00	710,096.00
MEDCASE	130,517.57	225,593.00

CEEP	126,488.77	64,290.00
Other (Bone Marrow Unit)	10,915.00	21,898.49
Military	605,550.00	575,449.00
TOTAL	2,344,060.55	2,281,021.00

Grants:

- a. U.S. Army Medical Research and Development Command - \$70,686.00
- b. Southwest Oncology Group - \$132,000.00
- c. Other Nonfederal Gifts - \$100,737.86
- d. CRDA - There were none for FY 94

Protocol Disposition FY 94

	<u>Terminated</u>	<u>Transferred</u>	<u>Completed</u>	<u>Ongoing to FY 95</u>
FY 77	-		0	1
FY 85	1		0	0
FY 86	3		1	1
FY 87	2		0	4
FY 88	4	0	0	3
FY 89	1	0	0	9
FY 90	4		3	29
FY 91	10		9	32
FY 92	24		15	29
FY 93	9		36	84
FY 94	<u>3</u>		<u>12</u>	<u>167</u>
	61		71	350

Training Protocols

	<u>Terminated</u>	<u>Transferred</u>	<u>Completed</u>	<u>Ongoing to FY 95</u>
FY 86	4		0	0
FY 87	2		0	0
FY 88	1		0	0
FY 89	1		1	0
FY 90	0		0	0
FY 91	0		0	0
FY 92	0		2	2
FY 93	1		1	3
FY 94	<u>9</u>		<u>4</u>	<u>4</u>
	18		8	9

Oncology Group Protocols

SWOG	4	32	126
POG	2	15	34
GOG	<u>0</u>	<u>2</u>	<u>44</u>
	6	49	204



Number of resident and fellowship programs: 23  
Number of residents and fellows with approved protocols: 95  
Number of approved protocols held by this group: 82

Other training programs that use Clinical Investigation: University of Texas Health Science Center at San Antonio; University of Texas, Austin; Academy of Health Sciences Physical Therapy Branch.

Number of approved protocols held by this group: 25

Number of hospital staff members with approved protocols: 182  
Number of approved protocols held by this group: 236

Drug evaluation/comparison studies: 94 (Does not include Oncology Group Protocols)

#### Significant Changes in the Last Year/Changes for the Future

We have become more proactive in recruiting investigators in the MEDCEN.

We are expanding our collaborative efforts with extramural sources. MRDC, the University of Texas Health Science Center at San Antonio and Austin, Cancer Therapy Research Center, and the State Chest Hospital are all collaborators.

#### Changes in Support of Growing Graduate Medical Education Requirements

There is a continuing requirement to have documented classroom hours devoted to research topics such as ethics, statistics, informed consent, protocol development, etc. These requirements are being met by going to the departments and offering tailored instruction for each units needs.

We continue to benefit from gifts and grants offered through the Jackson Foundation and organizations such as Facilitators of Applied Clinical Trials (FACT), the National Kidney Foundation and other not for profit organizations. Approvals for gifts of support are being processed in a more expeditious manner due to a better understanding of the approval process.

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#### Publications and Presentations Reported in 1994

Publications: 146  
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**DEPARTMENT OF THE ARMY  
Brooke Army Medical Center  
Fort Sam Houston, TX 78234-6226  
DEPARTMENT OF CLINICAL INVESTIGATION**

**PRESENTATIONS**

**DEPARTMENT OF CLINICAL INVESTIGATION**

Johnson, JM: Survey Research. Presented to Internal Medicine Residents, BAMC, 12 Oct 93.

Johnson, JM: Nursing Research Basic Skills Workshop (VA-BAMC Project), Oct 93, Audie L. Murphy VA Hospital, San Antonio, TX.

Lamiell, JM: Computer Auditing of Surgical Operative Reports Written in English. 17th Annual Symposium on Computer Applications in Medical Care, Washington DC, Nov 93.

Lamiell, JM: Parallel Methods for Medical Image Reconstruction from Projections. 97th Annual Meeting of the Texas Academy of Science, Houston, TX, Mar 94.

Lamiell, JM: von Hippel-Lindau Disease. 1st International Patient/Provider Conference on von Hippel-Lindau Disease, Kansas City, MO, Apr 94.

Lamiell, JM: Research for Graduate Medical Education. 41st Annual Symposium of the Society of Air Force Clinical Surgeons, San Antonio, TX, Apr 94.

**DEPARTMENT OF EMERGENCY MEDICINE**

Wellford, LA; Spears, G; Wellford, Landon: Computerized Teaching Module for ECG Interpretation. American College of Emergency Physicians, Chicago, IL. Oct 93.

Rodgers, KG: Teaching Children 911 - A Pilot Study. Triservice EM mtg at Riverwalk San Antonio.

Sheridan, BJ: Teaching Children 911 - A Pilot Study. Texas ACEP SA; SAEM Mtg, Washington DC.

Sheridan, BJ: CPC Case - Bilateral Blindness. Texas ACEP SA.

Collier, BW: Oral Board Exam Prep Crs at Triservice Sym of Emergency Medicine, 25 Mar 94.

## DEPARTMENT OF MEDICINE

### Cardiology Service:

Rubal, BJ; Bulgrin, JR: Comparison of Short-Time Fourier, Wavelet and Time-Domain Analyses of Intracardiac Sounds. The Univ of Texas at Austin Biomedical Engineering Program. 20 Jan 94, Austin, TX.

Bulgrin, JR; Posch, TE; Rubal, BJ; Moody, JM; Bauch, TD: Time-Frequency Analysis of Prosthetic Heart Valve Sounds. Texas Academy of Science 1994 Annual Meeting.

Rubal, BJ; Nottestad, SY; Mego, DM; Khan, N: Noninvasive Predictors of Biopsy Scores in Heart Transplant Patients. Texas Academy of Science 1994 Annual Meeting.

Moody, JM; Rubal, BJ; Posch, TE; Bulgrin, JR: Comparison of Cohen-Class Time-Frequency Distributions of Intracardiac Heart Sounds in Man. BAMC and Hughes Aircraft Corp, Fullerton, CA. American College of Cardiology.

Rubal, BJ; Bulgrin, JR; Posch, TE; Moody, JM; Gilman, JK. Sensitivity, Specificity and Accuracy of Time-Frequency Distributions Compared to Signal-Averaged ECG Criteria for Assessing Late Potentials. Experimental Biology 94, April 24-28, 1994, Anaheim, CA, by BJ Rubal, Ph.D.

### Dermatology Service:

Elston, DM. Bugs and Bites. Presented at the American Academy of Dermatology Annual Microbiology Meeting, Wash DC, 4 Dec 93.

Elston, DM. Alopecia and Folliculitis. Presented at the American Academy of Dermatology, Basic Dermatopathology Course, Washington, DC, 4 Dec 93.

Elston, DM. Office Microbiology Forum. Presented at the American Academy of Dermatology Annual Meeting, Washington, DC, 8 Dec 93.

Stiles, J; McCollough, MM; Hill, J. Basaloid Follicular Hematoma. Presented at the American Academy of Dermatology Annual Meeting, Washington, DC, 8 Dec 93.

Zimmerman, G. Plasma Cell Mastitis. Presented at the American Academy of Dermatology Annual Meeting, Washington, DC, 5 Dec 93.

Zimmerman, G. Cutaneous Side Effects of Taxotere. Presented at the Southern Medical Conference, New Orleans, LA, 29 Oct 93.

Burgess, JT. Goltz Syndrome. Presented at the American Academy of Dermatology Annual Meeting, Washington, DC, 5 Dec 93.

Grabski, WJ. Nasal Reconstruction. Presented at the American Academy of Dermatology Annual Meeting, Intermediate Surgery Course, Washington, DC, 5 Dec

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93.

Grabski, WJ. Local Flaps. Presented at the American Academy of dermatology Annual Meeting, Soft Tissue Laboratory, Washington, DC, 7 Dec 93.

Keller, RA. Dermatology in Military Operation. Presented at Camp Bullis C4 Course, 11 Oct 93 and 6 Dec 93.

Coot, NV; Keeling, JH. A 50 year History of Extra Mammary Paget's Disease. Presented at the American Academy of Dermatology Annual Course, Washington, DC, 4 Dec 93.

Biediger, TL; Grabski, WJ; McCollough, MM: Bilateral Pigmented Bowen's Disease of the Lower Lip. Submitted to International Journal of Dermatology.

Grabski, WJ; Salasche, SJ. Hemostatic Techniques and Materials. Chapter in Wheeland RG, Cutaneous Surgery. Published by WB Saunders, Philadelphia 1994; pp 189-198.

Vinson, RP: Metastatic Chordoma. Presented at the American Academy of Dermatology Annual Meeting, Washington, DC, 4 Dec 94.

Peake, MF: Diseases of the Skin. Presented at the Academy of Health Sciences 18 Delta Special Forces Medical Sergeant's Course, 4 Jan 94.

Grabski, WJ: Mohs Micrographic Surgery and Nasal Reconstruction. Presented at ENT Grand Grounds, Univ of TX Health Sci Cen at SA, Feb 94.

Coots, NV: Diseases of the Skin. Presented at Army Health Sciences SOMED Sergeant's Course, 30 Mar 94.

Coots, NV: Physical Examination of the Skin. Presented at Army Health Sciences SOMED Sergeant's Course, 30 Mar 94.

Coots, NV: All about Dermatology Residencies. Presented at Student National Medical Association, region III Convention, held at the Univ of TX Health Sci cen at SA, Oct 94.

Stiles, J: Case presentation: Bipolaris infection. Presented at the San Antonio Derm Society Meeting, 31 Mar 94.

Stiles, J: Case presentation: Histiocytosis X: Presented at the San Antonio Derm Society Meeting, 31 Mar 94.

Vinson, RP: Pityrosporum Cellulitis. Presented to the San Antonio Derm Society, Mar 94.

Vinson, RP: Septic emboli. Presented to the San Antonio Derm Society, Mar 94.



PRESENTATIONS (continued)

Vinson, RP: Cutaneous Herpes. Presented to the San Antonio Derm Society, Mar 94.

Vinson, RP: Avoiding Complications of Digital Tubular Gauze Dressing. Texas Med Assn Annual Meeting, Austin, TX May 94.

Coots, NV: Treatment of Extramammary Paget's Disease with 5FU Ionophoresis: A Novel Therapeutic Approach. Dermatology Section, Texas Med Assn Convention, Austin, TX 14 May 94.

Coots, NV: Diseases of the Skin. 18D SOMED Sergeants Course, Academy of Health Sciences, 27 May 94.

Grabski, WJ: Nasal Reconstruction: Surgical Grand Rounds, Darnall Army Community Hospital, Fort Hood, Tx, 16 Jun 94.

Peake, MF: Diseases of the Skin. Presented to the 18 Delta Special Operations Medic Course, AMEDDC&S, FSHT.

Keeling, JH: Melanoma: Practical Considerations and Management. Presented at the Amer Academy of Derm Academy '94 mtg, 3 Aug 94.

Stiles, JC: Case reports: Isolated Histiocytosis X and Bipolaris Infection in an Immunosuppressed Patient. Presented to the San Antonio Derm Society, March 94.

Anderson, LL: Cutaneous Manifestations of Internal Malignancy. Presented at the Scott & White Family Practice Review Course, Austin, TX, Apr 94.

Anderson, LL, et al: Aspergillus infection complicating wound healing in an immunocompetent host. Presented to the College of Mohs Micrographic Surgeons, San Diego, CA, May 94.

Anderson, LL, et al: Tattoo pigment mimicking metastatic malignant melanoma. Presented to the Society of Dermatologic Surgeons, San Diego, CA, May 94.

Anderson, LL; Grabski, WJ: Mohs Micrographic Surgery Surgical Grand Rounds, Fort Hood, TX, Jun 94.

Endocrinology Service:

Vigo, G; Carlin, K: Cell Culture to Test if McF-7 Breast Cancer Cells in Vitro are Independent of Thyroid Hormone, San Antonio ACP Mtg, May 94.

Chung, A; Carlin, K: The Effect of Tetrac and Triac Upon Murine Bladder Cancer Cells in Cell Culture. SA ACP Mtg May94.

General Medicine Service:

Marple, R: A Prospective Study of the Concerns and Expectations in Patients

PRESENTATIONS (continued)

with Common Symptoms. Army ACP, Orlando, FL, Nov 93.

Marple, R: Common Symptoms in Ambulatory Patients: Symptom Outcome and Patient Satisfaction. National Society General Medicine, Wash DC 28 Apr 94.

Infectious Disease Service:

Kazragis, R: Experimental Mouse Model of Lyme Disease: Action of Vancomycin. Infectious Disease Society America (ICAAC) New Orleans, LA Oct 93.

Schrank, J: Developing a Polymerase Chain Reaction to Histo-phosmosis. ICAAC (IDSA) Mtg Oct 93.

Longfield, R: A Strategy to Present OSHA Guidelines to Hospital Staff. ICAAC, New Orleans, LA, Oct 93.

Nephrology Service:

Wortham, WG: Acute and Chronic Renal Failure and Dialysis Therapy. Clinical Residency Program - Nursing Education Southeast Baptist Hospital, San Antonio 18 Feb 94.

Pulmonary Disease Service:

Hayes, JA: Effect of Xanthine Oxidase Depletion on Rat Diaphragm Function during Resistive Breathing. National Meeting of the American College of Chest Physicians, Nov 93. (Cecile Lehman Mayer Rsch Award Finalist)

Anders, GT. Comparison of Cancer Patients Treated with Nd: YAG Laser to Patients not Treated with Laser: Survival and Clinical Data. National Meeting of the Amer College of Chest Physicians, Nov 93.

Atkins, J: The Effect of Respiratory Frequency on Maximum Voluntary Ventilation (MVV). National Meeting of the American College of Chest Physicians, Nov 93.

Morris, MJ: The Effect of a Gas Mixture with Similar Viscosity and density as Oxygen on forced Expiratory Flow in Patients with COPD. National Meeting of the American College of Chest Physicians, Nov 93.

Anders, GT: Characteristics of Patients with Prolonged Survival after Nd:YAG Endobronchial Photoresection. Army Regional Meeting of the American College of Physicians, Nov 93.

Morris, MJ: The effect of a Gas Mixture with similar Viscosity and Density as Oxygen on forced Expiratory Flow in Patients with COPD. Army Regional Meeting of the American College of Physicians, Nov 93.

Kemp, KR: The Relative Effect of Gas Viscosity and Density on Forced Expiratory Flow in Patients with COPD. Army Regional Meeting of the American

PRESENTATIONS (continued)

college of Physicians, Nov 93.

Hayes, JA: Tungsten Supplemental Diet Prevents Diaphragm Fatigue with Resistive Breathing in Rats. Army Regional meeting of the American College of Physicians, Nov 93.

Loube, DI: A Comparison of Self-Reported Sleepiness and Snoring in Pregnant and Non-Pregnant Women. Army Regional Meeting of the American College of Physicians, Nov 93.

Chung, A: The Effect of TETRAC and TRIAC Upon Murine Bladder Cancer Cells and Cell Culture. First Annual San Antonio American College of Physicians Associates Program, San Antonio, TX, 12 May 94.

Vigo, G: Cell Culture to Test if MCF-7 Breast Cancer Cells in Vitro are Independent of Thyroid Hormone. First Annual San Antonio American College of Physicians Associates Program, San Antonio, TX 12 May 94.

Garcia, A: Validation of the Catheter (C) Semiquantitative Culture (SQC) Technique for Non-Staphylococcal Organisms. First Annual San Antonio, TX 12 May 94.

Grady, E: Incidence and Significance of Hospital-Acquired Anemia in a Tertiary-Care Military Teaching Hospital. First Annual San Antonio American College of Physicians San Antonio, TX 12 May 94.

Parisek, RA; Battafarano, D; Marple, R; Carpenter, M; Kroenke, K: How Well do General Internists and Primary Care Subspecialists Diagnose and Manage Common Musculoskeletal Complaints. First Annual San Antonio American College of Physicians Associates Program, San Antonio, TX 12 May 94.

Parisek, RA: Presented above also at Amer College of Rheumatology 58th Natl Scientific Meeting, Minneapolis, MN 26 Oct 94 and Army ACP 27 Oct 94 - 1st place winner in Associate's Competition.

**DEPARTMENT OF NURSING**

Noble, L., AN. Improving Functional Mobility Through Exercise. Third Annual Hogstel Gerontological Research Symposium, Ft Worth, TX, 15 Oct 93.

Daniels, N: Stress Management. Assn of Urological Nurses Convention, San Antonio, TX, Oct 93.

Reilly, M: Keynote Address, San Antonio Junior College Honors Graduation, San Antonio, 17 Dec 93.

Richard, L: Grantsmanship: The Lived Experience. Darnall Army Hospital Annual Nursing Research Day, Ft Hood, TX, 19 Nov 93.

Yoder, L: Career Developmental Relationships. Darnall Army Hospital Annual

PRESENTATIONS (continued)

Nursing Research Day, Ft Hood, TX, 19 Nov 93.

Hodge, N; Moody, J: Clinical Case Management in the AMEDD. AMSUS Convention, San Antonio, TX 16 Nov 93.

Richard, L: Managed Care. AMEDD Officers Advanced Course, AMEDD Center and School, San Antonio, TX, 22 Nov 93.

Hodge, N: Acute MI. UTHSC Critical Care Course, San Antonio, TX, Sep 93.

Yoder, L: Bone Marrow Transplant. University of Mary Hardin Baylor School of Nursing and US Army Recruiting Command, Belton, TX, 7 Mar 94.

Reilly, M: Application of New Techniques in Music, Imagery and Relaxation to Clinical Settings. Fifth International Symposium on Music and Medicine sponsored by International Society for Music, Society for Arts and Medicine and University of TX Health Sci Center at SA, 16-18 Mar 94.

Richard, L; Johnson, J; Captain, C: Basic Nursing Research Skills Workshop. Collaborative Offering sponsored by Audie Murphy Veterans' Administration and BAMC, 18 and 25 Mar 94.

Richard, L; Johnson, J; Captain, C; Holtzclaw, B: Local Hospital Facilities Research Utilization Update. SA Council of Nurse Researchers and Univ of TX Health Sci Cen at SA, 24 Mar 94.

**DEPARTMENT OF OBSTETRICS AND GYNECOLOGY**

Higby, K: Normal Values of Urinary Albumin and Protein Excretion During Pregnancy. Society of Perinatal Obstetricians, 24-29 Jan 94, Las Vegas, NV.

Higby, K: Varicella in Pregnancy. Grand Rounds, Bayne Jones Army Hospital, Fort Polk, LA, 22 Feb 94.

Gehlbach, D: Laparoscopic Management of Ectopic Pregnancy. Advanced Gynecologic Laparoscopy. USUHS, Bethesda, MD Mar 94.

Gehlbach, D: Complications of Laparoscopy. Advanced Gynecologic Laparoscopy, USUHS, Bethesda, MD Mar 94.

Mattern, V; Dupont, BR; Higby, K; Moore, CM: FISH Verification of a Complex Arrangement Involving a Recombinant Chromosome. 19th Annual Meeting of Cytogenetic Technologists, San Diego, CA 1994.

Moore, CM: Prenatal Diagnosis of a Complex Chromosome Rearrangement Involving Four Chromosomes. American Cytogenetics Conference, 4-6 May 94, San Diego CA.

**DEPARTMENT OF PATHOLOGY**

PRESENTATIONS (continued)

Smith, Joseph: Retrospective and Prospective Controlled Study of the Immunopathology of 18 Patients who Died of Epidemic Hemorrhagic Fever in Hubei Province, People's Republic of China. Society of Armed Forces Medical Laboratory Sciences, Reno, NV 13-16 Mar 94.

**DEPARTMENT OF PSYCHIATRY**

Clement, PF: Amnesia of Unknown Etiology, San Antonio, TX 21 Jan 94.

Brooks, FR: Impact of the Army Medical Department Reorganization on Delivery of Behavioral Health. Behavioral Science Post-graduate Short Course, Aug 94, San Antonio, TX.

Grill, D: Current Issues in Army Clinical Psychology. 1994 AMEDD Behavior Science Short Course, San Antonio, TX, 2 Aug 94.

Grill, D: The Military Psychologist and Patient Confidentiality. Amer Psychological Assn Annual Convention, Los Angeles, CA, 11 Aug 94.

**PREVENTIVE MEDICINE SERVICE**

Karwacki, J: Army Preventive Medicine & The Environment. UTAHSC MPH Program.

**DEPARTMENT OF PEDIATRICS**

Inscore, SC: Grand Rounds, UTHSCSA, Dept of ENT. Grand Rounds, UTHSCSA, 23 Mar 94.

Inscore, SC; Heiman, HS; Cieslak, TJ; Roscelli, JD; Potter, A; Glasow, P: Pediatric Advanced Life Support Course. Naval Hospital Corpus Christi, Corpus Christi, TX, 3-4 Feb 9.

Pick, TE: Update on POG protocol 8615, Large Cell Lymphoma. Pediatric Oncology Group, Fort Lauderdale, FL, 15-18 Apr 94.

Pick, TE: Update on POG protocol 8844, Neuroblastoma in Children. Pediatric Oncology Group, Fort Lauderdale, FL, 15-18 Apr 94.

Heiman, HS: Perinatal Outcome as a Function of Health Care Delivery Systems. Texas Vital Statistics Conference, Austin, TX, 5-7 Dec 93.

**DEPARTMENT OF RADIOLOGY**

Cawthon, M: Large Scale PACS Installation and Implementation in a Medical Center Environment. Southern Medical Association 87th Annual Scientific Assembly, New Orleans, LA, 28-31 Oct 93.

#### PRESENTATIONS (continued)

Cawthon, M: PACS in an Old Hospital: Brooke Experience. Radio-logical society of North America 79th Scientific Assembly and Annual Meeting. Chicago, IL, 28 Nov-3 Dec 93.

Chacko, AK: Lessons Learned from Hospital Wide PACS Deployed in Military Hospitals. 18th International Congress of Radiology in Singapore, 23-28 Jan 94.

Spirnak, JP: Gadolinium-Enhanced MRI and Tc-99m SPECT Evaluation of Hydroxyapatite Orbital Implants. 18th International Congress of Radiology in Singapore, 23-28 Jan 94.

Cawthon, MA: Personnel Training During Large Scale PACS Implementation. SPIE's Medical Imaging Symposium 1994 in Newport Beach, CA 13-18 Feb 94.

Cramer, TJ; Chacko, AK; McLarney, JK; Mogel, GT: Asymmetric Screen-Film with Flexible Grid and Conventional Chest Radiography in Critical Care. American Roentgen Ray Society Meeting in New Orleans, LA Apr 94.

Leckie, B; Cramer, TJ; Chacko, AK: Military Teleradiology: A Live Demonstration. American Roentgen Ray Society Meeting in New Orleans, LA Apr 94.

Sostre, G: Hepatobiliary Imaging Medical Center Hospital, San Antonio, Nuclear Medicine.

#### DEPARTMENT OF SURGERY

##### Anesthesiology & Operative Svc:

Anderson D. Burn Anesthesia. Grand Rounds Walter Reed AMC Anesthesia Svc, 7 Oct 93.

Sayson, S. Predicting Intubating Conditions with Mivacurium: A Comparison of Neuromuscular Blockade Monitoring at the Adductor Pollicis and the Orbicularis Oculi. American Society of Anes-thesiologists, Washington, DC, 13 Oct 93.

Chronister, T. Does Effect of Intrathecal Narcotics on Maternal Blood Pressure. American Society of Anesthesiologists, Washing-ton, DC, 13 Oct 93.

Hecker, R. Anesthesia Under Austere Conditions. American Osteo-pathic College of Anesthesiologists, Orlando, FL, 3 Nov 93.

Anderson, D. Burn Anesthesia. Community Medicine Conference, Sonthofen, Germany, 7 Nov 93.

Szigeti, C: Intravenous Fluid Preload is Not Necessary for Maintenance of Blood Pressure in Healthy Patients Receiving Spinal Anesthesia. Society for Ambulatory Anesthesia, 28 Apr - 1 May 94, Chicago, IL.

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Mongan, P: Desmopressin Decreases Blood Loss and Transfusion Therapy After High Risk CPB Procedures. International Anesthesia Rsch Society, 8 Mar 94, 68th Clinical and Scientific Congress, Orlando, FL.

Critical Care Service:

Jaffin, J: Medical Support in the Meuse Argonne. Third Annual Great War Interconference Seminar, Arlington, VA, 1-3 Oct 93.

Jaffin, J: Modern America's Wild West: A Military Surgeon and Urban Trauma. US Army Special Operations Command, Surgeon's Conf, Fayetteville, NC, 4-7 Oct 93.

General Surgery Service:

Miller, G. Extremity Sarcoma: Vascular Reconstruction Leading to Limb Salvage. San Antonio Vasc Society, San Antonio, TX 11 Nov 93.

Miller, G. Same subject to Military Vascular Society Meeting, Bethesda, MD, 9-10 Dec 93.

Miller, G. The Use of Colonoscopy in Colonic Pseudo Obstruction. Texas Medical Association Colon & Rectal Section, Houston, TX, May 93.

Miller, G. Same subject to Gary P. Wratten Surgical Symposium, Walter Reed AMC, Wash DC, Mar 92.

Miller, G. Colon Cancer: Racial Differences - Survival. Gary P. Wratten Surgical Symposium, Breckenridge, CO, Mar 93.

Ophthalmology Service:

Campagna, J. Optic Nerve/Glaucomatous Optic Neuropathy. UTHSCSA Ophthalmology Grand Rounds Lecture Series, San Antonio 23 Sep 94.

O'Hara, M. Pediatric Ocular Tumors & Syndromes. UTHSCSA Ophthalmology Grand Rounds Lecture Series, San Antonio 26 Aug 94.

Hollsten, D. Orbital Inflammation/Thyroid Orbitopathy. UTHSCSA Ophthalmology Grand Rounds Lecture Series, San Antonio 19 Aug 94.

Lloyd, W. Pathology of Congenital Anomalies/Phakomatosis. UTHSCSA Ophthalmology Grand Rounds Lecture Series, San Antonio 9 Sep 94.

Orthopaedic Surgery Service:

Bucknell, AL: Operative Management of Fractures. 12th Annual Residents Conference, Memphis, TN, 27 Aug 94.

PRESENTATIONS (continued)

Arrington, ED: DVT Prophylaxis Following Hip Fractures. 12th Annual Residents Conference, Memphis, TN, 25 Aug 94.

Otolaryngology Service:

Burton, D. Benign Neck Masses, Univ of Texas Health Science Center at San Antonio, TX, 26 Oct 93.

Ramirez, S. Hyoid Suspension and Inferior Osteotomies in OSAS Patients. 1993 Southern Medical Assoc Meeting, New Orleans, LA, 29 Oct 93.

Ramirez, S. Maxillofacial Trauma in Military Setting. 1993 AAFPRS Meeting, San Antonio, TX, 13 Nov 93.

Liening, D: Stapedectomy. UTSA Grand Rounds, San Antonio, TX, 8 Mar 94.

Burton, D: Gastroesophageal Reflux and Pediatric Airways. Visiting Professor, Scottish Rite Children's Hospital, Galveston, TX 25 Mar 94.

Hayes, DK: Vertical Partial Laryngectomy. UTHSCSA Grand Rounds, San Antonio, TX 5 Apr 94.

Romanow, JH: Orbital Complications of Sinusitis. UTHSCSA Grand Rounds, San Antonio, TX 19 Apr 94.

Liening, D: Non-Surgical Treatment of Acoustic Neuroma. UTHSCSA Grand Rounds, San Antonio, TX 10 May 94.

Burton, DH: Pediatric Tracheotomy. UTHSCSA Grand Rounds, San Antonio, TX 24 May 94.

Otto, R: Tissue Adhesives in Otolaryngology. UTHSCSA Grand Rounds, San Antonio, TX 7 Jun 94.

Ramirez, S: Pediatric Malignancies. UTHSCSA Grand Rounds, San Antonio, TX 21 Jun 94.

Liening, D: Persistent Labyrinthine Enhancement: Is Tumor Present? Meniere's Symposium, Snowmass, CO 17 Jul 94.

Liening, D: Relief of Hearing Loss Due to Rheumatoid Arthritis by Decompression. Meniere's Symposium, Snowmass, CO 17 Jul 94.

Liening, D: Tympanoplasty. UTHSCSA Grand Rounds SA TX 9 Aug 94.

Hayes, D: Scar Revision. UTHSCSA Grand Rounds, SA TX 2 Aug 94.

Urology Service:



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Thompson IM:

The Economic Impact of Stone Disease in the United States. Consensus Conference on Urolithiasis, National Institutes of Health, Bethesda, MD, 4 Oct 93.

Problems with the Current Staging System for Prostate Cancer. AUA Postgraduate Seminar, San Diego, CA, 9 Oct 93.

When to Abandon Conservative Management of Bladder Cancer. AUA Postgraduate Seminar, San Diego, CA, 10 Oct 93.

The Ideal Urinary Diversion. AUA Postgraduate Seminar, San Diego, CA, 10 Oct 93.

Potential Problems with the Early Detection of Prostate Cancer. American College of Surgeons Annual Meeting, San Francisco, CA, 11 Oct 93.

Press Conference - Announcement of Opening of the Prostate Cancer Prevention Trial, National Institutes of Health, Bethesda, MD. 13 Oct 93.

Early Detection of Prostate Cancer - Potential Problems with Screening. University of Toronto postgraduate course. Toronto, Canada, 23 Oct 93.

Chemoprevention of Prostate Cancer. Kimbrough Urological Seminar, San Diego, CA, 28 Oct 93.

Chemoprevention of Prostate Cancer. American Urological Association Allied Symposium. San Antonio, TX 6 Nov 93.

Chemoprevention of Prostate Cancer. Symposium on prostate cancer - USUHS - Palm Springs, CA, 4 Dec 93.

Early detection of Prostate Cancer. Symposium on prostate cancer - USUHS - Palm Springs, CA, 4 Dec 93.

Management of pT3 Prostate Cancer, Madigan AMC, Urology Grand Rounds, 2 Jun 94, Tacoma, WA.

Expectant Management of Localized Prostate Cancer. Puget Sound Urological Assn, 2 Jun 94, Tacoma, WA.

Treatment of Prostate Cancer. American Cancer Society Postgraduate Crs, 4 Jun 94, Seattle, WA.

Chemoprevention of Prostate Cancer. American Cancer Society Postgraduate Crs, 4 Jun 94, Seattle, WA.

Chemoprevention of Prostate Cancer. Grand Rounds, Univ of Washington School of Medicine, 5 Jun 94, Seattle, WA.

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Chemoprevention of Prostate Cancer. Grand Rounds. State Univ of New York, 5 Apr 94, Brooklyn NY.

Chemoprevention of Prostate Cancer - Educational Seminar American Society of Clinical Oncology Annual Meeting, 14 May 94.

Highlights of Prostate Cancer Presentations, American Urological Assn Annual Meeting, 18 May 94, San Francisco, CA.

Management of Complications of Prostate Cancer. Chairman, Postgraduate Course. American Urological Assn Annual Mtg, 18 May 94, San Francisco, CA.

Guidelines for the Management of Prostate Cancer. Presentation of the Prostate Cancer Panel Chairman. American Urological Assn Annual Mtg, 18 May 94, San Francisco, CA.

Chemoprevention of Prostate Cancer. Annual Cancer Prevention Mtg, Texas Tech Univ, 20 May 94, Lubbock, TX.

Chemoprevention of Prostate Cancer. Early Detection of Prostate Cancer. Annual Medical Oncology Symposium, Dayton, OH, 3 Feb 94.

Adjuvant Therapy for Locally Advanced Prostate Cancer. Scott and White Clinic, Temple, TX, 4 Feb 94.

The Early Detection of Prostate Cancer. Pros and Cons. Memorial Sloan-Kettering Cancer Center, New York, NY, 25 Feb 94.

The Early Detection of Prostate Cancer. Univ of Miami International Symposium on Prostate and Bladder Cancer. Orlando, FL, 10 Mar 94.

- Pros and Cons of Early Prostate Cancer Detection
  - Treatment Options for Low Stage Germ Cell Tumors
  - Chemoprevention of Prostate Cancer
  - Complications of Prostate Cancer - Management
- McDonald Seminar, Phoenix, AZ, 19 Mar 94.

Chemoprevention of Prostate Cancer. SUNY, Brooklyn, NY, 5 Apr 94.

Chemoprevention of Prostate Cancer - Educational Seminar. Amer Soc of Clin Oncology Annual Mtg, 14 May 94.

Renfer, L:

Magnetic Resonance Imaging changes with balloon dilation of the Prostate. Kimbrough Urologic Seminar, San Diego, CA, 29 Oct 93.

Diagnosis and staging of prostate and bladder cancer. Renfer, L. American Urological Association Allied Symposium. San Antonio, TX, 6 Nov 93.

Chapters in Books:

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Validation of a Food Frequency Questionnaire in Southern Black Females. Robin J. Tefft, American Public Health Assn, San Francisco, CA, 24-28 Oct 93.

Introduction to Nutrition Management Information Systems. Henley, Hannah. Hospital Food Service Specialist NCOIC Crs, FSHT, 8-12 Aug 94.

Field Nutrition and Field Feeding in Somalia, Skluzacek, Lori. Hospital Food Service Specialist NCOIC Crs, FSHT, 8-12 Aug 94.

Database Maintenance for TRIFOOD. Henley, Hannah. TRIFOOD Supervisors Crs, FSHT, 23-25 Aug 94.

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### **DEPARTMENT OF CLINICAL INVESTIGATION**

Merrill, GA; Poli, MA; Rivera, VR; Hewetson, JF. Detection of Ricin by Colorimetric and Chemiluminescent Elisa. Toxicon.

Lamiell, JM; Zhang, X: Parallel Methods for Medical Image Reconstruction from Projections. Proc Texas Academy of Science 97th Annual Meeting, Mar 94

Ward, JA; Lamiell, JM: Determination of Set Membership by Neural Networks. Proc Texas Academy of Science 97th Annual Meeting, Mar 94.

### **DEPARTMENT OF EMERGENCY MEDICINE**

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### Cardiology Service:

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Moore, CM; Dupont, BR; Mattern, VL; Higby, K: Prenatal Diagnosis of a Complex Chromosome Rearrangement Involving Four Chromosomes.

## DEPARTMENT OF PATHOLOGY

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## DEPARTMENT OF PEDIATRICS

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Battista, MA; Price, P; Kalhon, S: Effect of Pediatric Parenteral Aminoacid Mixture on Leucine and Urea Kinetics in Preterm Infants. Proceedings of the American Academy of Pediatrics Uniformed Services Pediatric Seminar, 13-17 Mar 94, page 232.

Greenberg, DN; Ascher, DP; Hensley, DM; Heiman, HS, Keith, JF; Yoder, BA: Sensitivity of Urine Antigen Tests for Diagnosis of Group B Streptococcal Bacteremia in Neonates. Proceedings of the American Academy of Pediatrics Uniformed Services Pediatric Seminar, 13-17 Mar 94, page 107 (Andrew Margileth Clinical Research Award Finalist)

Baumann, DA; Roscelli, JD; Potter, A: Incidence of Elevated Blood Lead Levels in Military Dependents. Proceedings of the American Academy of Pediatrics Uniformed Services Pediatric seminar, 13-17 Mar 94, page 220.

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Tiwary, CM: Use of Hormone/Placenta Containing Cosmetic Product(s) by Parents and/or Children Attending Pediatric Clinics: A Survey. Proceedings of the American Academy of Pediatrics Uniformed Services Pediatric Seminar, 13-17 Mar 94, page 257.

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## DEPARTMENT OF RADIOLOGY

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DEPARTMENT OF SURGERY

Anesthesiology Service:

Baumgarten, RK; Loughhead, DJ: Effect of Injectate Temperature on the Effectiveness of Isobaric Lidocaine for Inguinal Hernior-raphy. ASRA 94.

Cardiothoracic Surgery Service:

Cohen, DJ; Briceno, JC; Runge, RM; Murk, SE; Ottmers, SE. Monitoring of Blood Gases During Prolonged Experimental Cardiopulmonary Bypass and Their Relationship with Brain pH, PO<sub>2</sub> and PCO<sub>2</sub>. ASAIO Abstracts 23, 56, 1994.

Otolaryngology Service:

Lienine, DA. Comparison of Polydioxone and Silicone Plastic in the Prevention of Adhesive Otitis Media in the Mongolian Gerbil. AAO-HNS Mtg, Minneapolis, MN Oct 93 (Poster)

Romanow, JH. Multiple Linear Regression Analysis of Apnea Indices as a Function of Cephalometric Measurement. AAO-HNS Mtg, Minneapolis, MN Oct 93 (Poster)

Malis, DJ. Extranodal Paranasal Sinus Non-Hodgkins Lymphoma of the Head and Neck. AAO-HNS Mtg Minneapolis, MN Oct 93 (Poster)

Malis, DJ. Retained Bronchial Foreign Bodies. AAO-HNS Mtg Minneapolis, MN Oct 93 (Poster)

Johnson, RE. Tortuous Internal Carotid Artery Presenting as an Oropharyngeal Mass. AAO-HNS Mtg Oct 93 (Poster)

Balbuena, L: Eagle Syndrome. Presented at American Acad of Oto Mtg, San Diego CA 20 Sep 94 (Poster)

Lee, J: Recurrent Laryngeal Nerve Paralysis During Greenfield Filter Placement. Presented at Academy of Otolaryngology Mtg, San Diego CA 20 Sep 94 (Poster)

Urology Service:

Clark, J; Thompson, IM. Serum Cholesterol as a Risk Factor for Prostate Cancer. J Clinical Oncology (Abstract) in press.

Thompson, IM; Harris, MJ; Bishoff, JT; Reyes, A: Preoperative PSA and Prostate Biopsy Gleason's Grade is Predictive of Benign Pelvic Lymph Nodes in Men with Prostate Cancer. J Urol 151-340A, 1994.

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Harris, MJ; Bishoff, JT; Reyes, A; Thompson, IM. Preoperative PSA and Prostate Biopsy Gleason's Grade Predictive of Benign Pelvic Lymph Nodes in Men with Prostate Cancer. J Urol, 151:340A, 1994.

Crawford, ED; Eisenberger, MA, Blumenstein, B; McLeod, DG; Culkin, DJ; Bueshen, AJ; Thompson, IM; Lowe, BA. Treatment of Histologically Confirmed D2 Prostate Cancer - A Comparison of Bilateral Orchiectomy With or Without Flutamide (Intergroup Study 0105). J Urol, 151:238A, 1994.

Clark, J; Thompson, I. Serum Cholesterol as a Risk Factor for Prostate Cancer. J Clin Oncol, 13:246, 1994.

# Detail Summary Sheet

Date: 15 Nov 94 Protocol Number C-18-88 Status: Ongoing

Title: Development of an Indirect Chemiluminogenic Enzyme Linked Immunoassay (CELIA) for Demonstrating Conformational Changes in a Model Protein

Start date: 16 Dec 88	Estimated completion date:
Principal Investigator: Gerald A. Merrill	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Clinical Investigation	Associate Investigator(s): Paul M. Horowitz, PhD, UTHSC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost: \$4,690.00

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To develop monoclonal antibodies to rhodanese, a well characterized model protein, and use these antibodies in the development of an indirect soluble chemiluminescent enzyme linked assay system.

To assess the binding affinities of anti-rhodanese monoclonal antibodies for their epitomes and demonstrate conformational changes involving the rhodanese epitomes by monitoring changes in binding affinities.

Technical Approach: The study plan is to develop a series of antibodies to use in an attempt to better understand the structure-function relationships of a model protein, rhodanese (thiosulfate;cyanide sulfurtransferase). Knowledge

C-18-88 (continued)

of the relationships of between protein structure and protein functions will provide insight into the manipulation of proteins that have medical relevance, including hormones and enzymes. Such knowledge might then permit synthesis via genetic engineering of designer rescue proteins that could be used therapeutically.

Progress: A synthesized peptide corresponding to the rhodanese N-terminal sequence (1-17) have been shown to interact with nascent rhodanese bound to ribosomes of an in vitro transcription/translation system. The interaction prevents DNAJ-dependent release of the peptide from the ribosomes required for effective folding of the peptide into active enzyme. Studies showing that a monoclonal antibody to rhodanese can detect its epitope on an inactive folding intermediate have been concluded. The intermediate is compact based on intrinsic fluorescence data, indicating that major refolding into domains has occurred. This compact inactive conformer slowly rearranges to assume a native-like, based on intrinsic fluorescence, but still inactive conformer on which the epitope recognized by the monoclonal antibody is not expressed. The activity is rapidly regained by addition of thiosulfate to facilitate local conformational changes about the active site. The monoclonal antibody can be used to reflect the progression from compact inactive enzyme to native-like inactive enzyme and thus can serve as a means to monitor folding mechanisms.

# Detail Summary Sheet

Date: 15 Nov 94 Protocol Number: C-4-91 Status: Ongoing

Title: Development of a Bioluminescent Assay of Extreme Sensitivity for Detection and Quantitation of Ricin

Start date: 16 Nov 90	Estimated completion date:
Principal Investigator: Gerald A. Merrill, Ph.D	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Clinical Investigation	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To develop a solid phase enzyme-linked sandwich assay of high sensitivity for the detection and quantitation of ricin which is based on avidin-biotin technology, enzymatic generation of ATP, and the sensitivity of photon counting detection of ATP via the bioluminescent luciferin-luciferase (firefly).

Technical Approach: A solid phase enzyme linked immunoassay for quantitation of ricin utilizes the chemiluminescence of a luminol derivative which emits light at alkaline pH following the removal of a phosphate group by the action of alkaline phosphatase and concentrate the toxin which may be present in very low concentrations. The quantitation of ricin that is immobilized involves addition of biotinylated anti-ricin followed by excess avidin-alkaline phosphatase which binds to biotin very tightly. The quantitation of the alkaline phosphatase can be either colorimetric or can be measured via luminescent methods with increased sensitivity using AMPPD as the substrate.

Progress: Modification of the assay to detect ricin with increased sensitivity has been proposed. The modification involves an immuno-PCR technique which has been designed. The use on ricin detection will be as a model for use in detection of botulism toxin which requires extreme sensitivity, but which cannot be developed at BAMC due to the restrictions on use of botulism toxin. A request for \$10,000 in funding for FY 1996 has been submitted to USAMRIID for development of the assay system.

# Detail Summary Sheet

Date: 4 Nov 94 Protocol Number: C-25-91 Status: Ongoing

Title: Automated Screening of Western Blot Densitometry Scan for the Detection of Type-Specific Herpes Virus Antibodies.

Start date: 6 Feb 91 Estimated completion date: 6 Feb 95

Principal Investigator: John A. Ward, PhD Facility: Brooke Army Medical Center, Texas

Department/Service: Department of Clinical Investigation Associate Investigator(s): Julia K. Hilliard, PhD

Key Words:

Cumulative MEDCASE cost: Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine if the application of digital signal processing and artificial neural networks (ANN) can be used to distinguish B virus antibodies from herpes simplex antibodies in human sera.

Technical Approach: Train ANNs with an input consisting of preprocessed densitometer scans of western blots (WBs) from serum samples run against B virus antigen. Preprocessing involves the application of signal analysis techniques: mapping the densitometer scans to a common molecular weight axis, filtering to remove high and low frequency noise and emphasize peaks, normalizing to eliminate amplitude distortion, windowing to zero the high and low molecular weight ends of the scan, and cross-correlating and aligning the signals to eliminate phase shifting.

Progress: Two techniques (correlation analysis and ANNs) have been tested. Both presented problems. Wbs showed higher correlations between different sera run on the same blot than between the same sera run on different blots. ANNs were susceptible to phase shift errors and noise not represented in the training set. In the next year, Wbs of control (BV + rhesus, BV-rhesus, BV + human, HSV1 + human, HSV2 + human and negative human) sera and 180 sample (6 X 30) sera will be run against BV, HSV1 and HSV2 antigens. Since the 35 to 73 kD region appears to be critical for discrimination between virus types, each WB will be divided into three regions (200 to 73 Kd, 73 to 35 Kd, 35 to 14.3 Kd). This will provide 6 X 3 X 3 = 54 regional Ag-Ab cross correlation coefficients which will be input to a neural network. This will provide an internal control for variation in batches of antigen, control sera and

immuno-electrophoretic technique.

# Detail Summary Sheet

Date: 24 Oct 94                      Protocol Number: C-49-91                      Status: Ongoing

Title: The Use of Polymerase Chain Reaction (PCR) to Detect Hepatitis C in Units of Donor Blood

Start date: 9 Apr 91	Estimated completion date:
Principal Investigator: Curtis L. Yeager, MAJ, MS	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Of Clinical Investigation	Associate Investigator(s): William F. Nauscheutz, CPT, MS Victor Tryon, PhD
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To develop an assay to test for Hepatitis C virus (HCV) in units of donated blood collected at BAMC, using polymerase chain reaction and robotic technology.

Technical Approach: We intend to develop methods which combine the technology of robotics and high sensitivity and specificity of the polymerase chain reaction (PCR) to detect Hepatitis C virus (HCV) in approximately 300 units of donor blood daily. We will develop the system such that test results will be available the same day the units are drawn.

Progress: We still await the arrival of some equipment ordered.



# Detail Summary Sheet

Date: 24 Oct 94 Protocol Number: C-58-91 Status: Ongoing

Title: Preparation of Large and Small Unilamellar Vesicles and Interaction with Magainin

Start date: 4 Jun 91	Estimated completion date:
Principal Investigator: Earl Grant, Jr., MAJ, MS	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Clinical Investigation	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To establish the means and verify the methodology that will produce well-defined liposomes for use as model membranes for the study of protein/peptide-lipid interactions and as potential drug carriers to aid in cancer therapy.

Technical Approach: Large unilamellar vesicles of various lipid compositions will be prepared by the reverse phase ether evaporation method. Small unilamellar vesicles of various lipid compositions will be prepared by sonication. The functional integrity of the vesicles can be assessed by monitoring the release of entrapped 6-carboxyfluorescein in the absence and presence of Triton X-100.

Progress: We continue to maintain the capability to produce small unilamellar vesicles, however, we do not have the equipment to prepare large unilamellar vesicles by the reverse phase ether evaporation method. The needed equipment is being requisitioned and alternative methods are being investigated.

# Detail Summary Sheet

Date: 24 Oct 94 Protocol Number: C-91-91 Status: Ongoing

Title: Molecular Detection of Bloodborne Pathogens in Blood for Transfusion with Emphasis on Hepatitis C.

Start date: 7 Oct 91	Estimated completion date:
Principal Investigator: Curtis L. Yeager, MAJ, MS	Facility: Brooke Army Medical Center
Department/Service: Department of Clinical Investigation	Associate Investigator(s): William F. Nauscheutz, CPT, MS
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Review results:

Objective(s): To develop methods which combine the speed and precision of robotics and the high sensitivity and specificity of gene amplification strategies to detect RNA from the hepatitis C virus in 300 units of volunteer donor blood daily.

Technical Approach: Research in this proposal is designed to adapt gene amplification techniques to a clinical diagnostic format capable of operating at a process level (300 plus tests per day). Research to be conducted includes identification and development of unique nucleic acid probes and primers, testing of amplification techniques, development of solid phase nucleic acid capture assays; adaptation of radiometric assays to machine-read fluorometric testing and side-by-side comparison of the molecular diagnostic assays developed versus the standard serological assay.

Progress: We are currently awaiting approval of research funding by Medical Research and Development Command.

# Detail Summary Sheet

Date: 24 Oct 94      Protocol Number: C-93-20      Status: Ongoing

Title: Establishment of a Polymerase Chain Reaction (PCR) Nucleic Acid Amplification capability Within the Department of Clinical Investigation, BAMC

Start date: Feb 93	Estimated completion date: Feb 95
Principal Investigator: Curtis L. Yeager, Ph.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Clinical Investigation	Associate Investigator(s): N/A
Key Words: Polymerase chain reaction Taq polymerase, Ethidium bromide Agarose gel electrophoresis	
Cumulative MEDCASE cost: 0	Estimated cumulative OMA cost: Approved \$2725.00      Used \$1457.01

Number of subjects enrolled during reporting period:   N/A    
Total number of subjects enrolled to date:   N/A    
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To establish a working PCR gene amplification capability. It will result in the capability to specifically amplify a positive control bacteriophage gene without contamination by irrelevant nucleic acids. Demonstration of the desired product will include separation of the amplification products by agarose gel electrophoresis and identification by product size as seen after ethidium bromide staining.

Technical Approach: No subjects involved. Controls for the reaction are contained within the kits and include a distilled water negative control and a specific bacteriophage gene positive control. Experimental design/methods; data collection and details included in protocol.

Progress: The initial PCR was successfully accomplished and resulted in the contamination-free amplification of a Lambda bacteriophage gene. Continuing to optimize those reactions as well. Analysis of amplification products by agarose gel electrophoresis and ethidium bromide staining has been successful and both this and PCR are being taught to DCI staff.

# Detail Summary Sheet

Date: 24 Oct 94 Protocol Number: C-93-95 Status: Ongoing

Title: Inoculation with Pentavalent (ABCDE) Botulinum Toxoid

Start date: 16 Jul 93	Estimated completion date:
Principal Investigator: James M. Lamiell, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Clinical Investigation	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 1  
 Periodic review date: Dec 93 Review results: \_\_\_\_\_

Objective(s): Immunization of one volunteer who will be working with botulism toxin at Fort Detrick, MD.

Technical Approach: The vaccine will be obtained from the centers for Disease Control (CDC). The initial vaccination series will be given 0.5 ml deep subcutaneously at 0, 2, and 12 weeks. Forty-eight hours after each injection, the injection site will be observed by the principal investigator. The first booster will be given 0.5 ml deep subcutaneously 12 months after the first injection of the initial series. Subsequent boosters will be given 0.5 ml deep subcutaneously at 2 year intervals, based on antitoxin titers. Any reactions or side effects will be observed and reported to the CDC.

Progress: One subject has received the initial series of 4 immunizations given as 0.5ml deep subcutaneous doses at 0, 2, 12 weeks and booster at one year. After 12th week, neutralization titer was 0.08 units; 0.02 is considered protective. Booster given at one year has not been re-titered.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-75                      Status: Ongoing

Title: Evaluation of Terry Fox Metho-Cult H433 and Gibco BRL Human Bone Marrow Stem Cell Differentiation Media

Start date:	Estimated completion date:
Principal Investigator: Enid Davey	Facility: Brooke Army Medical Center, Texas
Department/Service: Clinical Investigation	Associate Investigator(s): Svetislava J. Vukelja, M.D.
Key Words: bone marrow stem cells, Gibco BRL Medium	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 10  
 Total number of subjects enrolled to date: 10  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objectives: To determine if Gibco BRL Medium supports greater differentiation of bone marrow stem cells than Terry Fox Medium.

Technical Approach: The study will be conducted in two phases as outlined in protocol.

Progress: A preliminary study has been done using Terry Fox's Metho-Cult #4431, as to growth, size and differentiation, compared to Gibco-BRL media.

# Detail Summary Sheet

Date: 25 Oct 94 Protocol Number: C-93-40 Status: Ongoing

Title: An Evaluation of Nafcillin for the Initial Treatment of Cellulitis

Start date: 24 Dec 92	Estimated completion date:
Principal Investigator: Curtis Hunter, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Emergency Medicine	Associate Investigator(s): Kevin Rodgers, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 10  
 Total number of subjects enrolled to date: 10  
 Periodic review date: Review results:

Objective(s): To evaluate the effectiveness of oral antibiotics in treating cellulitis and preventing subsequent admission of patients with cellulitis. Compare the efficacy of an initial parenteral dose of antibiotics in preventing the subsequent admission of patients with cellulitis, as compared to those patients who do not receive parenteral antibiotics. Compare the efficacy of an initial dose of parenteral antibiotics in treating more rapidly those patients with cellulitis, as compared to those patients who do not receive antibiotics.

Technical Approach: This will be a randomized, prospective study. Patients with cellulitis deemed appropriate for outpatient therapy will be randomized at the beginning of the study to one of two treatment regimens. Patient eligibility, exclusion criteria and study plan outlined in protocol.

Progress: A preliminary study has been done using Terry Fox's Metho-Cult #4431, as to growth, size and differentiation, compared to Gibco-BRL media.

# Detail Summary Sheet

Date: 3 Aug 94 Protocol Number: C-60-86 Status: Ongoing

Title: The Natural History of HTLV-III Infection and Disease in a United States Military Population.

Start date: 25 Jun 86	Estimated completion date:
Principal Investigator: C. Kenneth McAllister, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Dept. of Medicine/Infectious Disease	Associate Investigator(s):
Key Words: HTLV-III	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 60 new  
 Total number of subjects enrolled to date: 570  
 Periodic review date: n/a Review results:

Objective(s): 1) To assess the impact of HTLV-III infection on fitness for duty (deployability, military readiness and retention) by systematically defining the natural disease progression in individuals with documented HTLV-III infections in the general military population (active duty, dependents and retirees).

2) To form an information basis and a study cohort upon which number other studies can be built (i.e., drug treatment of HTLV-III, etc.).

Technical Approach: Each HTLV-III infected individual will be staged according to the Walter Reed Staging Classification. The only additional requirements of individuals enrolled in this study are (1) additional information gathered from each individual as a consequence of this study will be centralized in a common data base; (2) serum and CSF will be stored at WRAIR for Future testing.

Progress: The study continues; approximately 570 patients have been enrolled. Again, his is a descriptive study of Army HIV patients and the clinical cause of their HIV infection.

# Detail Summary Sheet

Date: 1 Oct 94                      Protocol Number: C-52-87                      Status: Ongoing

Title: Autologous Bone Marrow Rescue in Patients with Acute Leukemia and Lymphoma Using Ex Vivo Marrow Treatment with 4-hydroxyperoxycyclophosphamide (4-HC).

Start date: 13 May 87	Estimated completion date:
Principal Investigator: Svetislava J, Vukelja, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Medicine/Oncology	Associate Investigator(s): Terry E. Pick, COL, MC Allen Potter, LTC, MC Barbara Reeb, DAC Robert G. Whiddon, Jr., LTC, MS
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4  
 Total number of subjects enrolled to date: 6  
 Periodic review date: 20 May 91      Review results: Continue

Objective(s): 1) To evaluate autologous marrow rescue after intensive therapy in patients with acute leukemia and lymphoma in second remission or subsequent remission or in early relapse.

2) To study the effects of ex vivo bone marrow purging utilizing 4-HC on malignant cells, marrow stem cells, and relationship to subsequent engraftment times.

3) To study the acute toxic effects of the preparative regimens.

Technical Approach: To be eligible for this study, all patients must have a diagnosis of acute leukemia or aggressive histology lymphoma and have relapsed after therapy. Bone marrow should be harvested when the patient is in remission.

Therapy will follow the schema outlined in the study protocol.

Progress: Study ongoing for eligible patient enrollment.



# Detail Summary Sheet

Date: 1 Sep 94                      Protocol Number: C-62-87                      Status: Ongoing

Title: Development of an Autologous Bone Marrow Rescue Program (Master Protocol).

Start date: 25 Jun 87	Estimated completion date:
Principal Investigator: Svetislava J. Vukelja, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Medicine/Oncology	Associate Investigator(s): Terry E. Pick, COL, MC Allen Potter, LTC, MC Robert G. Whiddon, Jr, LTC, MS Barbara Reeb, DAC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost: \$19,404.00

Number of subjects enrolled during reporting period: 39

Total number of subjects enrolled to date: 206

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To develop an autologous bone marrow rescue program at Brooke Army Medical Center.

2) To participate in research and clinical studies individually as well as part of the Southwest Oncology Group and Pediatric Oncology Group.

3) To establish a competent marrow rescue service for all eligible DOD patients for present clinical indications and future indications, i.e., radiation exposure.

Technical Approach: Bone marrow stem cells will be obtained by multiple bone marrow aspirations under general anesthesia. The marrow will be prepared by accepted methods and frozen for future reinfusion. (This is the master protocol for the autologous bone marrow transplant program.

Progress: Study remains ongoing for eligible patient enrollment.

# Detail Summary Sheet

Date: 1 Sep 94                      Protocol Number: C-64-87                      Status: Ongoing

Title: Evaluation of Patients with Human Immunodeficiency Virus (HIV) Seropositivity Detected by Screening for the Presence and Potential Etiology of Exercise Intolerance.

Start date: 21 Jul 87	Estimated completion date:
Principal Investigator: James E. Johnson, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Medicine/Pulmonary	Associate Investigator(s): Gregg T. Anders, MAJ, MC Herman M. Blanton, MAJ, MC Eleanor Ayala, DAC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 48  
 Periodic review date: 19 Oct 92      Review results: Continue

Objective(s): Patients with HIV seropositivity have been noted to have exercise intolerance at an early stage when they are otherwise asymptomatic. The goals of this study are as follows: 1) To determine the prevalence of complaints of exercise intolerance and dyspnea in the study population. 2) To document whether abnormalities of exercise physiology exist in these patients complaining of exercise intolerance. 3) To evaluate these patients for potential causes of exercise intolerance such as early opportunistic pulmonary infection or lymphocytic interstitial pneumonitis (LIP).

Technical Approach: All active duty patients admitted to the HIV ward or referred to the HIV clinic for evaluation will be considered eligible for the study. These patients will be given a questionnaire on the day of admission including questions regarding exercise tolerance and dyspnea as well as previous lung, heart and muscle diseases. The response to these questions will be used for further patient selection. All participants will undergo gallium scan of the lungs, pulmonary function testing to include lung volumes and a  $D_LCO$ , cycle ergometry pulmonary exercise testing and bronchoalveolar lavage (BAL). The BAL fluid will be divided and submitted for the following: 1) staining for routine cytological evaluation (for evidence of viral infection) as well as for AFB and GM stains; 2) culture for AFB, Fungi, CMV and HIV virus; 3) HIV antigen testing for comparison to peripheral blood titers; 4)

C-64-87 (continued)

quantitation of lymphocytes, PMNs, monocytes as well as lymphocyte subsets particularly OKT4 and OKT8.

Progress: - No new patients have been added during the review period. Request protocol remain open for patient accrual.

# Detail Summary Sheet

Date: 3 Oct 94                      Protocol Number: C-11-88                      Status: Terminated

Title: Effect of Thyroid Replacement on Lipid Profile - Differences Associated with Keeping the TSH in Low Normal as Compared to Upper Normal Euthyroid Range.

Start date: 2 Dec 87	Estimated completion date:
Principal Investigator: Department of Medicine/Endocrinology	Facility: Brooke Army Medical Center, Texas
Department/Service: Albert M. Thomason, COL, MC	Associate Investigator(s):
Key Words: Euthyroid	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 3  
 Periodic review date: 25 Feb 91      Review results: Continue

Objective(s): To demonstrate a difference in the lipid profile of euthyroid patients treated with higher or lower doses of thyroid replacement therapy.

Technical Approach: Patients being treated with thyroid replacement are enlisted as volunteers. Individual patients have their TSH levels adjusted by varying their thyroid replacement dose to above 3.5 mcIU or below 1.1 mcIU/ml depending on whether the initial value was above or below the mean euthyroid value of 2.3 mIU/ml. The patient is maintained at the lower or higher TSH value for 3 months as determined by monthly measurements. Then, the patient's serum lipid profile (cholesterol, triglyceride, and HDL cholesterol) is determined after a 14 hour fast x 2. Subsequently, the patient has his dosage of thyroid replacement adjusted to keep his TSH value in the opposite end of the euthyroid range from which it was initially. After three months of stabilization of the new value of TSH level, the plasma lipid profile is repeated. Subsequently, the patient again has his TSH value adjusted to a relatively higher or lower value depending on where he started initially. After another 3 month period of stabilization, lipid profile is obtained again.

Progress: Study terminated due to lack of patient volunteers.

# Detail Summary Sheet

Date: 7 Nov 94 Protocol Number: C-19-88 Status: Ongoing

Title: Effect of Oral Agents vs Insulin Therapy on Lipid Profile.

Start date: 13 Jan 88	Estimated completion date:
Principal Investigator: Albert M. Thomason, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Medicine/Endocrinology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 1  
 Periodic review date: 19 Mar 91 Review results: Continue

Objective(s): To demonstrate whether low density lipoprotein cholesterol and total cholesterol-high density lipoprotein cholesterol ratios are worse in Type I diabetics treated with insulin as compared to oral agents.

Technical Approach: 30 patients being treated with oral hypoglycemic agents would be enlisted as volunteers. For the first 3 months, the patient would be followed on his/her usual oral hypoglycemic agent to determine average HGB A1C and lipid profile values. Subsequently the patient would be taken off the oral hypoglycemic agent and placed on human insulin therapy in such a dosage as to keep the Hgb A1C value as near as possible to the value the patient had while being treated with oral hypoglycemic agent. After 4 months on insulin therapy the patient's lipid profiles for the previous 3 months would be averaged to compare the lipid profile while on oral hypoglycemic therapy. Subsequently, the patient would be taken off insulin and restarted on the same dose of hypoglycemic agent as previously taken. At the end of 4 months, the patient's lipid profile would be averaged as before.

Progress: We are still lacking in recruitment of volunteers. More effort will be made to recruit volunteers which as stated previously is very difficult without being able to provide some kind of compensation.

# Detail Summary Sheet

Date: 15 Aug 94                      Protocol Number: C-47-88                      Status: Terminated

Title: Percutaneous Recanalization of Human Coronary Arteries with Balloon-Expandable Intracoronary Grafts (BEIG). (Collaborative Study with University of Texas Health Science Center)

Start date: 25 Apr 88	Estimated completion date:
Principal Investigator: William Wright, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Medicine/Cardiology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 23  
 Total number of subjects enrolled to date: 29  
 Periodic review date: 25 May 91      Review results: Continue

Objective(s): 1) To determine the safety of the stent by evaluating reporting clinical complications associated with its placement. 2) To determine the effectiveness of the stent by evaluating patients for long-term patency rates. Patency will be compared with results reported in the literature for PTCA alone. In addition, results will be compared with follow-up of a concomitant group of control patients treated by PTCA.

Technical Approach: This study is designed as a prospective survey following placement of a Balloon Expandable Intracoronary Stent in a coronary artery. The stent will initially be implanted in patients with confirmed collateral blood flow to the distal portion of the stenotic coronary artery.

Progress: This study has been closed since 1992. Results of this trial led to the opening of the randomized stress trial (results to be published this month-Aug-Circ).

# Detail Summary Sheet

Date: 3 Aug 94 Protocol Number: C-23-89 Status: Terminated

Title: Retrospective Analysis of Acute Exacerbations of Chronic Renal Failure. --

Start date: 27 Jan 89	Estimated completion date:
Principal Investigator: Steven F. Gouge, MAJ MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Medicine/Nephrology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 212  
 Periodic review date: 3 Feb 93 Review results:

Objective(s): To determine the risk factors for, clinical presentations and outcomes of acute exacerbations of chronic renal failure; and to compare these variables in patients to patients with chronic renal failure without exacerbation and patients with acute renal failure without prior chronic renal failure.

Technical Approach: Records of patients with a discharge diagnosis of acute renal failure, CRF, or both during the period 1986 and 1987 will be reviewed.

Progress: Study terminated due to departure of principal investigator. Dr. Gouge has PCS'd and no one in the Nephrology Service is going to take over the study.

# Detail Summary Sheet

Date: 14 Sep 94      Protocol Number: C-63-89      Status: Ongoing

Title: What is the Value of Fecal Hemoccult Blood Tests Performed at the Time of Digital Rectal Examination

Start date: 26 Apr 89	Estimated completion date:
Principal Investigator: Shailesh Kadakia, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s): MAJ Charles Cohan, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost: \$750.00

Number of subjects enrolled during reporting period: 89  
 Total number of subjects enrolled to date: 37  
 Periodic review date: 20 May 91      Review results: Continue

Objective(s): To determine the clinical meaning and usefulness of positive fecal occult blood tests (Hemoccult Method) discovered at the time of routine digital rectal examination.

Technical Approach: Adult patients over the age of 40 with positive hemoccult tests obtained on normal appearing stool obtained at rectal examination are eligible. Patients are offered the standard care which includes full evaluation of the lower GI tract and possibly of the upper GI tract. Stool Hemoccult II samples are collected on 3 consecutive days in the usual manner with standard dietary and drug restrictions. Hemoquant assays to determine the total amount of hemoglobin in the stool is also determined on the same stool samples. Findings at colonoscopy and/or upper endoscopy are noted.

Progress: Since the last reporting on 15 Dec 93, ten additional patients have been enrolled from Tripler Army Medical Center, Hawaii, by Charles Cohan, M.D. He has collected data on all 99 patients enrolled since the beginning of the study. The data is being analyzed and the result will be available within the next several weeks.



# Detail Summary Sheet

Date: 25 Aug 94                      Protocol Number: C-107-89                      Status: Ongoing

Title: Phase I Trial of Intrapleurally Administered Alpha Interferon in Malignant Pleural Effusions.

Start date: 14 Aug 89	Estimated completion date:
Principal Investigator: Howard A. Burris, III, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Medicine/Oncology	Associate Investigator(s): Timothy J. O'Rourke, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4  
 Total number of subjects enrolled to date: 17  
 Periodic review date: thru 31 Dec 93      Review results: Continue

Objective(s): 1) To determine the tolerance to and toxicity of intrapleural administration of Intron-A in patients with malignant pleural effusions.  
 2) To determine antitumor activity of Intron-A intrapleurally as evidenced by control of pleural effusions.

Technical Approach: Treatment of eligible patients will follow the schema outlined in the study protocol.

Progress: Toxicity consists of mild flu-like symptoms being observed at the current dose level of 50 million units/m2. Anticipate closure at this dose level after enrollment of another 2-4 patients.

# Detail Summary Sheet

Date: 1 Oct 94                      Protocol Number: C-3-90                      Status: Ongoing

Title: Differences in Response to Thiazide-Induced Hyponatremia by Gender.

Start date: 7 Dec 89	Estimated completion date: Jun 94
Principal Investigator: MAJ Kevin C. Abbott, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Medicine/Nephrology	Associate Investigator(s): Steven F. Gouge, MAJ, MC Daniel Gavin, CPT, MC
Key Words: Hyponatremia, gender, thiazides, free water clearance, antidiuretic hormone	
Cumulative MEDCASE cost: \$4800	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 7  
Total number of subjects enrolled to date: 9  
Periodic review date: n/a                      Review results: \_\_\_\_\_

Objective(s): To determine the differences, if any, between healthy elderly males and females in response to a water challenge test before and after the administration of hydrochlorothiazide.

Technical Approach: Eight men and eight women (power analysis projections from current results allowed this change from the original estimate of ten men and ten women), age 55 and above, with no concurrent hypertension or diabetes will be studied. Baseline blood tests will be drawn for serum sodium and potassium levels as well as thyroid function tests and a baseline water challenge test in which they will drink 20 cc/kg of ideal body weight of fresh water followed by a four hour timed urine collection for urine electrolytes and osmolality. Before the water load and after four hours, blood samples will be drawn for serum sodium, potassium, antidiuretic hormone, prolactin, diuretic levels and atrial natriuretic factor.

Progress: Principal Investigator has been deployed. Protocol status unknown.

# Detail Summary Sheet

Date: 24 Oct 94 Protocol Number: C-21-90 Status: Completed

Title: A Double Blind Clinical Evaluation of the Safety and Efficacy of Fenticonazole Cream (2% Fenticonazole Nitrate) in treatment of Tinea Pedis.

Start date: 25 Jan 90	Estimated completion date:
Principal Investigator: Larry E. Becker, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Medicine/Dermatology	Associate Investigator(s): Richard A. Keller, MD
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 40  
 Total number of subjects enrolled to date: 40  
 Periodic review date: Review results:

Objective(s): To determine the safety and efficacy of Fenticonazole Cream in the treatment of tinea pedis.

Technical Approach: Approximately 40 patients will be selected for participation in this study. Male and female patients eighteen years of age and older with clinical signs of moderate to severe tinea pedis will be treated for four weeks once daily with vehicle controlled placebo or active agent. Follow-up visits at 2 and 4 weeks and again at 6 weeks (2 weeks after completing treatment) will be used to evaluate clinical and laboratory evidence of success of therapy.

Progress: Forty patients were enrolled in the study. One patient was dropped from the study at visit 2 (week 2). He had a significant worsening of his disease. Repeat KOH scraping showed the new blisters on his feet to be positive (due to fungal infection worsening). The coded medication sheet for this patient was opened confirming the suspicion that the patient was getting placebo. He was terminated from the study and placed on active drug; responding nicely. Eight patients were initial visit culture negative so cannot be evaluated. One patient missed 2 visits. One patient did not return for final 6 week evaluation leaving a total of 29 patients completing all requirements of the study.

Clinical Response: IMPROVEMENT

	<50%	>50%	
Vehicle	11	1	
Active Drug	5	12	.0012 Fisher's Exact Prob

Analysis of Variance Techniques and Categorical Analysis Techniques will be used to further evaluate the study when the data is combined with results from several other centers using identical protocol.

# Detail Summary Sheet

Date: 4 Oct 94 Protocol Number: C-22-90 Status: Completed

Title: Phase II Clinical Trial of Anagrelide in Thrombocytosis of Myeloproliferative Disorders (70014), Compassionate Use. (Replaced by C-93-19)

Start date: 25 Jan 90	Estimated completion date:
Principal Investigator: COL Timothy J. O'Rourke, MC	Facility:   Brooke Army Medical Center, Texas
Department/Service: Department of Medicine/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 3  
 Periodic review date: 20 May 91 Review results: Continue

Objective(s): To determine the ability of anagrelide to effectively reduce platelet numbers in patients with thrombocythemia, to determine the dose of anagrelide which would be required to reduce platelet numbers and the dose needed to maintain them at or close to normal levels and to evaluate the safety of this compound.

Technical Approach: As outlined in the protocol.

Progress: A single patient continues enrolled on this study; has experienced no adverse side effects and is doing well.

# Detail Summary Sheet

Date: 3 Oct 94                      Protocol Number: C-24-90                      Status: Ongoing

Title: Induction of TNFa and IL-1 in Human Tuberculosis.

Start date: 5 Feb 90	Estimated completion date:
Principal Investigator: Gregg T. Anders, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Pulmonary Disease	Associate Investigator(s): J. William Kelly, MAJ, MC C. Kenneth McAllister, COL, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost: \$18,300.00 (R&D)

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: 20 May 91      Review results: Continue

Objective(s): The objective of this study is to determine the extent of tumor necrosis factor-alpha (TNF-a) and interleukin-1 (IL-1) production association with human tuberculosis. Peripheral blood monocytes cells (PBMC) from patients with positive purified protein derivative (ppd) skin reactions or active tuberculosis will be compared with healthy controls (PPD negative) by in vitro stimulation with mycobacterial antigens and killed Mycobacterium tuberculosis and the concurrent production of TNF-a and IL-1 measured by ELISA.

Technical Approach: Patients and healthy controls (staff volunteers) will be phlebotomized approximately 50 ml of blood by peripheral venipuncture. In vitro antigen stimulation of PBMC and measurement of TNF-a and IL-1 production by ELISA will be performed.

Progress: Study remains ongoing for patient accrual.

# Detail Summary Sheet

Date: 15 Aug 94      Protocol Number: C-40-90      Status: Ongoing

Title: Prostaglandin Excretion of Radiocontrast Induced Acute Renal Failure.

Start date: 12 Mar 90	Estimated completion date:
Principal Investigator: William G. Wortham, MAJ	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Nephrology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2  
 Total number of subjects enrolled to date: 3  
 Periodic review date: 3 Feb 93      Review results: Continue

Objective(s): To determine if prostaglandins are diminished in response to radiocontrast administration in the human subject. Further to determine if the decrement, if noted, correlates with a change in renovascular resistance, renal blood flow and/or creatinine clearance during the acute period surrounding radiocontrast administration.

Technical Approach: Participants will be admitted 24 hours prior to cardiac catheterization for collection of a 24-hour urine sample for sodium and prostaglandin metabolites, thromboxane B2 and 24-hour creatinine. In addition, they will undergo a nuclear determination via plasma clearance, <sup>125</sup>I Hippuran and DTPA to determine renal blood flow as well as GFR via radionuclide study 4-6 hours prior to catheterization, they will receive half-normal saline at approximately 125 cc/hour if not contraindicated by volume status. At cardiac catheterization, a determination of central venous pressure will be necessary. immediately after contrast administration, a second spot renin and catechol determination will be made. After cardiac catheterization a 24-hour urine will be collected for prostaglandin metabolites and sodium and creatinine as well as routine serum creatinine and electrolytes. An <sup>125</sup>I Hippuran and DTPA for determination of renal plasma flow and glomerular filtration will be obtained 24 hours post cardiac catheterization.

Progress: Study ongoing but still has not been actively pursued due to time

C-40-90 (continued)

constraints of myself, Nuclear Medicine Service and significantly by inability to recruit patients from the Cardiology Service. Two patients were recently recruited. Protocol is progressing slowly.



# Detail Summary Sheet

Date: 15 Aug 94                      Protocol Number: C-71-90                      Status: Ongoing

Title: High Dose Chemotherapy with Autologous Bone Marrow Support for Selected Advanced Solid Tumors.

Start date: 7 Jun 90	Estimated completion date:
Principal Investigator: Svetislava J. Vukelja, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 7  
 Total number of subjects enrolled to date: 11  
 Periodic review date: 20 Sep 91 Review results: Continue

Objective(s): To determine the toxicity, time to marrow reconstitution, responsive rate, and time to treatment failure of high-dose combination chemotherapy with carboplatin, etoposide, and cyclophosphamide followed by autologous marrow infusion in eligible patients with advanced metastatic solid tumors.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: No patients entered this year would like to keep study open.

# Detail Summary Sheet

Date: 15 Aug 94                      Protocol Number: C-90-90                      Status: Ongoing

Title: Intensive Therapy and Autologous Bone Marrow Transplant with 4-HC Purging in Acute Myelocytic Leukemia (ACL) and Acute Lymphocytic Leukemia (ALL).

Start date: 30 Aug 90	Estimated completion date:
Principal Investigator: Svetislava J. Vukelja, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2  
 Total number of subjects enrolled to date: 6  
 Periodic review date: 1 Oct 92                      Review results: \_\_\_\_\_

Objective(s): To determine the effects of autologous transplantations with 4-HC-treated marrow on hematopoietic reconstitution, actuarial relapse rate, and leukemia-free survival in pediatric and adult patients (< 65 y/o) with AML in second or third remission, and ALL in second or third remission.

Technical Approach: Fourteen patients under age 60 will be studied. Therapy will follow the schema outlined in the study protocol.

Progress: 4-HC is no longer available for purging. So we continue to do the transplant without 4-HC purge (addendum was submitted more than 1 1/2 years ago; however many patients have BM stored that was previously purged when 4-HC was available. Thus, we need to keep this protocol open. All patients have relapsed to date.

# Detail Summary Sheet

Date: 1 Oct 94                      Protocol Number: C-11-91                      Status: Ongoing

Title: The Effect of Oxygen Breathing Upon Lung Machines in Patients with Emphysema.

Start date: 3 Feb 93	Estimated completion date:
Principal Investigator: James E. Johnson, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/ Pulmonary	Associate Investigator(s): Kevin Kimke, CPT, MC Wayne Honeycut, MAJ, MC H.M. Blanton, MAJ, MC Gregg T. Anders, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 40  
 Total number of subjects enrolled to date: 58  
 Periodic review date: 19 Oct 92                      Review results: \_\_\_\_\_

Objective(s): To study the effects on lung mechanics of breathing 50% oxygen balance nitrogen versus breathing 21% oxygen balance nitrogen in a group of emphysematous patients with moderately severe disease.

Technical Approach: Patients undergo forced vital capacity, thoracic gas volume, airway resistance and compliance measurement before and after breathing 21% O<sub>2</sub> and 50% O<sub>2</sub> (double-blinded).

Progress: No new patients have been added. Recently Southern Medical Journal accepted a manuscript containing some of this work. Protocol remains open.

# Detail Summary Sheet

Date: 1 Oct 94 Protocol Number: C-12-91 Status: Completed

Title: The Effect of Magnesium on Ventricular Rate Control in Atrial Fibrillation.

Start date: 11 Dec 90	Estimated completion date:
Principal Investigator: Janet V. Hays, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Cardiology	Associate Investigator(s): MAJ Maureen Arendt, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 15

Total number of subjects enrolled to date: 15

Periodic review date: Jun 93 Review results: See below

Objective(s): 1) To assess the immediate degree of rate control achieved with parenteral magnesium in patients with atrial fibrillation with a rapid ventricular response.

2) To assess the cumulative degree of rate control achieved at four hours with parenteral magnesium and digoxin in patients with atrial fibrillation with a rapid ventricular response.

Technical Approach: This study will examine the immediate effect of an intravenous bolus of magnesium sulfate on the ventricular response in patients with atrial fibrillation. It will also examine the combined effect of magnesium and digoxin on these same patients. It is expected that magnesium alone will cause an immediate decline in the ventricular rate compared to the placebo-controlled group r that the magnesium-digoxin combination will provide significantly greater rate control in four hours than may be achieved by digoxin alone. Patients will be drawn from those admitted to the Telemetry or Coronary Care Units with atrial fibrillation who meet the inclusion criteria.

Progress: Study wsa performed in patients with new onset atrial fibrillation determined by the amount of rate control achievable by IV Magnesium Sulfate. This was compared to the amount of rate control achievable by placebo, and in

C-12-91 (continued)

combination with Digoxin. The study was closed as enough patients were recruited to give adequate power to the study. The results of the study were published in the July 1994 issue of Annals of Emergency Medicine, Vol. 24, 1, pg. 61-64. Results obtained were that with 2 gms of Magnesium given IV, ventricular rates in atrial fibrillation declined  $16 \pm 7\%$  within 5 minutes. This was statistically significant compared to placebo, and was comparable to the rate control achievable with Digoxin at 4 hours (ventricular rate declined  $18 \pm 9\%$ ). With combined Magnesium/Digoxin therapy, overall ventricular rate declined  $26 \pm 7\%$ , which was not significant compared to Digoxin alone. No significant side effects or complications were noted during this study. No further funding is needed for this study. A copy of the published article is included for your review.

# Detail Summary Sheet

Date: 1 Oct 94 Protocol Number: C-13-91 Status: Ongoing

Title: A Randomized, Double-Blind, Placebo Controlled Trial of the Effect of Lovastatin on the Incident of Primary Coronary Heart Disease in Patients with Mild to Moderate Elevations in Total and LDL-Cholesterol in Combination with Low HDL-Cholesterol.

Start date: 11 Dec 90	Estimated completion date: 1998
Principal Investigator: Joe M. Moody, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Cardiology	Associate Investigator(s): Edwin J. Whitney, M.D., WHMC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2 Aug 94  
 Total number of subjects enrolled to date: Over 5 thousand = 6,609  
 Periodic review date: Review results: safety board review ->  
 continue study no adverse safety data yet

Objective(s): To investigate whether chronic treatment with lovastatin in patients without clinical evidence of coronary heart disease, slight to moderately elevated total and LDL cholesterol and low HDL-cholesterol will decrease the rate of fatal CHD of nonfatal myocardial infarction over a period of at least five years.

Technical Approach: Participants will be asked to maintain a standard low-fat and low-cholesterol diet throughout the study under the guidance of a dietician. Participants will be randomly assigned to either the placebo group or treatment group. The later group will receive 20 or 40 mg of lovastatin. Following initial evaluation at the Wilford Hall Wellness Clinic, they will be asked to return at six week intervals for the first eighteen months and then every six months thereafter. Lab tests will be performed at every follow-up visit.

Progress: There have been no complications, misadventures or adverse drug reactions as defined by regulation. Specifically, there have been 110 patient withdrawals due to CPK or liver function elevations. Twenty-nine patients have been withdrawn (2%). Studies of similar nature have encountered withdrawal of eight to twelve percent with an average of ten percent. This withdrawal ratio is exceptionally low. None of the patients were withdrawn due to events attributable to the study medication. Due to lagging

C-13-91 continued

recruitment, approval to enroll civilians and civil servants was obtained from the Air Force Surgeon General, as well as the Air Staff on 26 June 1991. Civilian participants do not become eligible for care in the military system by participating in this study. Enrollment is now 18.2% complete with 1,225 men (84%) and 232 women (16%). Estimated completion date is May 1997. As of 2 August 94: Since December 1993, enrollment stable at 6600 patients. There are over 90 endpoints, no analysis yet, safety data not adverse.

# Detail Summary Sheet

Date: 3 Oct 94                      Protocol Number: C-14-91                      Status: Ongoing

Title: Active Immunization of Early HIV Patients with Recombinant GP-160 HIV Protein: Phase II Study of Toxicity Immunotherapy, In Vivo Immunoregulation and Clinical Efficacy.

Start date: 8 Jan 91	Estimated completion date:
Principal Investigator: J. William Kelly, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Infectious Disease	Associate Investigator(s): C. Kenneth McAllister, COL, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 47  
 Total number of subjects enrolled to date: 59  
 Periodic review date: 5 Nov 91                      Review results: \_\_\_\_\_

Objective(s): To conduct a Phase 2 trial of the recombinant human immunodeficiency virus (HIV) envelope glycoprotein, GP160 candidate vaccine, in patients with early HIV infection (Walter Reed Stage 1-2). Specific objectives include: 1) to continue to evaluate the immunogenicity and toxicity of this product; 2) to determine the parameters predictive of immuneresponsiveness; and 3) to determine the clinical efficacy of immunization with GP160 in the treatment of early HIV infection.

Technical Approach: As outlined in the study protocol.

Progress: All patients are four years into followup. Recommend continuation for continued followup.



# Detail Summary Sheet

Date: 1 Oct 94                      Protocol Number: C-16-91                      Status: Completed

Title: High Dose Cytosine Arabinose (HIDAC), Fractionated Total Body Irradiation (FTBI) and Autologous Bone Marrow Transplantation (BMT) to Treat Patients with Acute Lymphoblastic Leukemia (ALL) in Second Hematologic Remission: A Phase II Study.

Start date: 14 Jan 91	Estimated completion date:
Principal Investigator: Svetislava J. Vukelja, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Hem Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 0  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine the incidence of non-engraftment and of leukemic relapse in patients receiving autologous BMT (ABMT) following the ex vivo depletion of leukemic lymphoblasts from the autologous marrow using the immunogenetic purging technology.

Technical Approach: As outlined in the study protocol.

Progress: On this study, we entered only one patient. The protocol from Florida is closed. Would like to keep this open if possible, for those rare patients but I am not sure we can get immunomagnetic purging, so we should probably close this study.

# Detail Summary Sheet

Date: 25 Aug 94                      Protocol Number: C-21-91                      Status: Completed

Title: Prospective Correlative Clinical Trial of Response to 5-FU in a Newly Developed Chemoresponse Assay Versus Clinical Response to Continuous 5-FU Infusion in Patients with Refractory Breast Cancer.

Start date: 6 Feb 91	Estimated completion date:
Principal Investigator: Howard A. Burris, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Hem Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: thru 31 Dec 92                      Review results: \_\_\_\_\_

Objective(s): To conduct a prospective correlative clinical trial of the newly developed ChemoResponse Assay in patients with refractory breast cancer.

Technical Approach: As outlined in the study protocol.

Progress: Accrual was completed and the results presented to the Food and Drug Administration in fall of 1993. A 20% response rate was observed with 5FU which matched the predictive results of the drug. Consideration for final approval by the FDA is in progress. Two patients at BAMC will continue to be treated until progression of their disease is observed.

# Detail Summary Sheet

Date: 15 Aug 94 Protocol Number: C-28-91 Status: Ongoing

Title: Exercise Induced Oxyhemoglobin Desaturation as a Predictor of Nocturnal Desaturation in Chronic Obstructive Pulmonary Disease Patients.

Start date: 6 Feb 91	Estimated completion date:
Principal Investigator: Wayne T. Honeycutt, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Pulmonary	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 13

Total number of subjects enrolled to date: 33

Periodic review date: 19 Oct 92 Review results:

Objective(s): To determine whether exercise induced oxyhemoglobin desaturation in moderate to severe chronic obstructive pulmonary disease (COPD) patients can predict those who will have significant nocturnal desaturation.

Technical Approach: Approximately 40-50 subjects will be studied. Each patient will undergo an initial history and physical examination. Pulmonary function tests will be performed on the SensorMedics Horizon System to include pre- and post-bronchodilator forced vital capacity (FVC) and FEV1. Lung volumes and diffusion capacity for carbon monoxide will be measured. Resting arterial blood will be obtained in the supine position on room air. Desaturation with exercise will be evaluate during cardio-pulmonary testing using the Minolta Pulse-Oximeter. Nocturnal respiratory excursions, nasal airflow, ECG and oxyhemoglobin saturation will be monitored with an ambulatory system.

Progress: Request protocol to continue as ongoing. The principal investigator has PCS'd. However, a request for change in principal investigator will be submitted to the IRB and protocol will be restarted.

# Detail Summary Sheet

Date: 1 Oct 94 Protocol Number: C-34-91 Status: Terminated

Title: Central Aortic Blood Pressure Variability During Cardiac Catheterization.

Start date: 28 Feb 91	Estimated completion date:
Principal Investigator: Bernard J. Rubal, Ph. D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Cardiology	Associate Investigator(s): Mr. H. Herbert Peel
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 5  
 Total number of subjects enrolled to date: 5  
 Periodic review date: Review results:

Objective(s): Retrospective study to evaluate the variability in central aortic systolic, diastolic and mean blood pressures to within  $\pm 1$  mm Hg in a consecutive series of 500 patients registered in the high-fidelity hemodynamic tape library at Brooke Army Medical Center.

Technical Approach: This is a retrospective study in which archived data is processed, A/D converted and computer analyzed.

Progress: Only a small number of patients have been entered to date due to limited access to clinical hemodynamic recording systems. Progress has, however, been made in computer software for this project. A decision by medical maintenance to disconnect the physiologic recording system in the 3rd floor cath lab has temporarily made it impossible to review and digitize data from the archive library. This project will continue as soon as laboratory equipment is refurbished. Study completed, terminate.

# Detail Summary Sheet

Date: 4 Oct 94                      Protocol Number: C-57-91                      Status: Completed

Title: Spontaneous Bacterial Peritonitis Following Elective Esophageal Variceal Sclerotherapy: A Prospective Trial.

Start date: 4 Jun 91	Estimated completion date:
Principal Investigator: John G. Carrougner, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Gastroenterology	Associate Investigator(s): Shailesh C. Kadakia, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: \_\_\_\_\_ Review results: No subjects

Objective(s): To evaluate the incident of spontaneous bacterial peritonitis (SBP) after elective esophageal variceal sclerotherapy (EVS).

Technical Approach: All patients with previous variceal bleeding who are receiving elective EVS and have ascites on physical examination will be eligible for the study. Patients will be admitted to the hospital and, following detailed history and physical exam, a paracentesis will be done. This will be sent for total cell count, polymorphonuclear count, total protein and albumin, cytology, aerobic and anaerobic cultures, and gram stain. The diagnosis of SBP will be made if the PMN count is 250/mm<sup>3</sup> or greater and/or positive ascitic fluid cultures.

Progress: No subjects have been enrolled. This study should be closed.

# Detail Summary Sheet

Date: 25 Oct 94 Protocol Number: C-62-91 Status: Terminated

Title: Treatment of Refractory Ulcers in Epidermolysis Bullosa Using Cultured Epidermal Allografts.

Start date: 4 Jun 91	Estimated completion date:
Principal Investigator: Wallace B. Smith, CPT. MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/ Dermatology	Associate Investigator(s): Jerome C. Hill, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2  
Total number of subjects enrolled to date: 2  
Periodic review date: Review results:

Objective(s): To successfully harvest and culture epidermal kartinocytes from the parent of a child with epidermolysis bullosa and develop a multilayer epidermal allograft to be used to cover nonhealing erosions.

Technical Approach: Epidermal allografts from cells obtained from a skin biopsy performed on the parent of a child with junctional epidermolysis bullosa will be isolated and grown. The cells thus obtained will be planted on plastic tissue culture plates containing Kartinocyte Growth Medium which has been developed for the growth of kartinocytes. We will attempt manipulations of the media to induce the growth of multilayer epidermal sheets which will be transplanted into nonhealing eroded areas on the child with junctional epidermolysis bullosa.

Progress: Both principal and associate investigator have PCS'd from BAMC. There has been no activity on this study for the past two years. Study is terminated.

# Detail Summary Sheet

Date: 4 Oct 94 Protocol Number: C-65-91 Status: Completed

Title: Phase I Trial of Tetraplatin Administered for Five Consecutive Days Every 28 Days.

Start date: 24 Jul 91	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2  
 Total number of subjects enrolled to date: 2  
 Periodic review date: Review results:

Objective(s): 1) To determine the maximum tolerated dose of Tetraplatin administered on a daily x 5 every 28 days schedule.

2) To determine the qualitative and quantitative toxicities of Tetraplatin on this schedule.

3) To determine the recommended dose for Tetraplatin on this schedule in Phase II trials.

Technical Approach: This is a phase I study of tetraplatin administered on a daily x 5 schedule. Dose levels are 1, 2, 3.3, 5, 7, 9, and 11 mg/m<sup>2</sup>.

Progress: Study is completed and the results have been published. No patients continue on treatment.

# Detail Summary Sheet

Date: 1 Oct 94                      Protocol Number: C-68-91                      Status: Terminated

Title: High Dose Cyclophosphamide, Etoposide, and Carmustine with DTIC and Autologous Marrow Rescue for Myeloma and Relapsed or Refractory Lymphoma, A Phase I-II Study.

Start date: 30 Jul 91	Estimated completion date:
Principal Investigator: Svetislava J. Vukelja, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Oncology	Associate Investigator(s): W. Jeffrey Baker, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 0

Periodic review date:                      Review results:                     

Objective(s): 1) To determine the complete response rate and survival of patients with relapsed or refractory Hodgkin's and non-Hodgkin's lymphoma treated with maximum tolerated dose of DTIC in combination with high dose cyclophosphamide, etoposide, and carmustine with autologous bone marrow rescue.

2) To determine the complete response rate and survival of patients with multiple myeloma treated with the maximum tolerated dose of DTIC in combination with high dose cyclophosphamide, etoposide, and carmustine with autologous bone marrow rescue.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: There have been no patients entered on this study. Study is closed.



# Detail Summary Sheet

Date: 1 Oct 94                      Protocol Number: C-71-91                      Status: Terminated

Title: The Polymerase Chain Reaction in the Diagnosis of Histoplasmosis.

Start date: 30 Aug 91	Estimated completion date: Dec 93
Principal Investigator: John H. Schrank, Jr, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Infectious Disease	Associate Investigator(s): Victor V. Tyron, Ph. D. C. Kenneth McAllister, Jr., COL, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To apply the polymerase chain reaction (PCR) in the detection and rapid diagnosis of histoplasmosis.

Technical Approach and Progress: The project consists of two experimental Phases:

a. Sequencing of amplified DNA to identify *H. capsulatum*-specific 18S ribosomal gene sequences. At present, we have sequenced the entire 1700bp gene from the G186AS *H. capsulatum* strain. A unique extra 400 base pair area was identified which seems to be contained by only this strain. We are currently attempting to sequence other strains to see if they also contain this extra 400bp piece.

b. Amplification of *H. capsulatum* DNA using organism-specific primers from organism in culture. We have chosen several unique primers from the sequenced gene and are testing them and modifying the actual amplification process in an attempt to increase the sensitivity and specificity of the assay.

Progress: Data analysis is complete. Results to be published.

# Detail Summary Sheet

Date: 25 Aug 94	Protocol Number: C-85-91	Status: Completed
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Title: Open Label Dose-Tolerance Study of Intravenous Ilmofofosine Administered by a 120 Hour Continuous Infusion Every 21 Days to Patients with Cancer Refractory to Standard Treatment.

Start date: 30 Sep 91	Estimated completion date:
Principal Investigator: Howard A. Burris, III, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Oncology	Associate Investigator(s): Timothy O'Rourke, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2

Total number of subjects enrolled to date: 2

Periodic review date: thru 31 Dec 92 Review results: \_\_\_\_\_

Objective(s): To determine the maximum tolerated dose of ilmofofosine when administered intravenously as a 120-hour continuous infusion every 21 days and to describe the toxicity of ilmofofosine when administered on the schedule described above.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This trial has completed accrual. Dose limiting toxicities included both hepatotoxicity and renal toxicity. Antitumor activity was seen in patients with ovarian, and non-small cell lung cancer. Phase II trials in these tumor types are underway. Results of this trial were presented at the ASCO meeting in Dallas, May 94.

# Detail Summary Sheet

Date: 15 Aug 94 Protocol Number: C-94-91 Status: Completed

Title: Evaluation of the Effect of Forceps Size on the Adequacy Specimens Obtained by Transbronchial Biopsy.

Start date: 7 Oct 91	Estimated completion date:
Principal Investigator: James E. Johnson, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Medicine/Pulmonary	Associate Investigator(s): Gregg T. Anders, MAJ, MC H.M. Blanton, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: 19 Oct 92 Review results: \_\_\_\_\_

Objective(s): To determine the relative diagnostic yield of bronchoscopic biopsy performed with either small or large smooth edged forceps.

Technical Approach: Each patient will have 3 biopsies done with the large and 3 biopsies done with the small forceps in randomized order. If more tissue is needed based on visual inspection of the material, one or more additional biopsies will be taken with each forceps. Biopsies taken with each of the two forceps will be submitted to pathology for examination. The pathologist will be blinded as to which forceps was used for each biopsy.

Progress: About 30 patients were studied with a finding of significantly more tissue obtained with the large forcep. This manuscript was published in the most recent issue of the American Review of Respiratory disease.

# Detail Summary Sheet

Date: 16 Aug 94 Protocol Number: C-92-5 Status: Terminated

Title: Pharmacodynamic Doppler Determination of Mitral Valve Area in Patients with Significant Aortic Insufficiency

Start date:	Estimated completion date:
Principal Investigator: MAJ David M. Mego, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s): LTC Joseph P. Johns, MC
Key Words:	
Cumulative MEDCASE cost: 0	Estimated cumulative OMA cost: 0

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 2  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To assess the hemodynamic effects of amyl nitrite in patients with combined mitral stenosis and aortic regurgitation, and to assess the accuracy of Doppler-determined mitral valve areas during these effects.

Technical Approach: Study will involve five patients with combined mitral stenosis and aortic insufficiency who are undergoing diagnostic cardiac catheterization.

Progress: Two patients were enrolled before our capability to perform high-fidelity catheterization was temporarily interrupted while awaiting construction of the third floor cath lab. The lab is now completed and we will resume enrollment of patients as they are identified.

# Detail Summary Sheet

Date: 14 Sep 94                      Protocol Number: C-92-11                      Status: Ongoing

Title: Household Transmission of Hepatitis C Virus in Military Populations

Start date: Jan 92	Estimated completion date: Dec 95
Principal Investigator: LTC Shailesh Kadakia, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s): MAJ Thomas Kepczyk, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 12 - consisting of  
 Total number of subjects enrolled to date: patients and 9 household  
 Periodic review date: \_\_\_\_\_ Review results: contacts

Objective(s): Study will consist of enrolling anti-HCV-positive individuals and anti-HCV-negative individuals with a diagnosis of chronic NANE hepatitis and their household contacts.

Technical Approach: Three (3) index cases tested positive for anti-HCV. The serum samples were submitted for further testing to include anti-HCV by ELISA, as well as by RIBA and finally by PCR to detect HCV-RNA. These samples were obtained from 3 index cases and 9 additional household contacts. Total of 56 index patients from BAMC, FAMC, WRAMC, and TAMC have been included in the study with 84 household contacts.

Progress: Since the last reporting on 15 Dec 93, no further patients have been enrolled in th study at BAMC. The data has been analyzed in 50 anti HCV positive patients and 83 household members from four Army Medical Centers to include BAMC, TAMC, Fitzsimons and Walter Reed and US Army Medical Research Institute of Infectious Diseases at Ft Dietrick. Of the total index cases as well as household contacts, 6 spouses have anti HCV, two of the six had independent risk factors for HCV infection and were excluded from statistical analyses. Thus, four of 47 spouses had detectable HCV markers of infection, a rate of 8.5 percent. This prevalence was greater tan the 0.54 percent observed among health blood donors for a P value of less than 0.0001. HCV RNA

C-92-11 (continued)

was present in 43 of 50 (86%) index patients and in 4 of 6 (67%) infected spouses. Preliminary six month follow-up data in 18 families with 0 conversion in male spouse (none sexual partner) complete family member. These results show that household exposure to a HCV-infected family member is a risk factor for recording HCV infection, particularly among sexual partners of HCV infected individuals.

This paper has been submitted for publication to Viral Hepatitis and liver disease journal and has been accepted for publication.

# Detail Summary Sheet

Date: 15 Aug 94                      Protocol Number: C-92-13                      Status: Completed

Title: Use of APACHE II Score to Predict Length of Mechanical Ventilation in Medical Intensive Care Patients

Start date:	Estimated completion date:
Principal Investigator: CPT James M. Brassard, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Pulmonary Disease	Associate Investigator(s): LTC James E. Johnson, MC LTC Greg Anders, MC LTC Herman M. Blanton, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 79  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine in a prospective fashion the correlation of first day APACHE II scores in patients admitted to an intensive care unit for acute respiratory failure secondary to ARDS, COPD. Pneumonia or Cardiogenic Pulmonary Edema with eventual duration of requirement for mechanical ventilation.

Technical Approach: APACHE (Acute Physiology, Age, Chronic Health Evaluation) Scores were derived from data obtained within 24 hours of ICU admission for patients admitted with the diagnosis of nonoperative respiratory disease. Mean scores were determined for 3 groups. 1-not intubated, 2- mechanical ventilator <14 days; 3-mechanical ventilator >14 days.

Progress: Study completed with an enrollment of 79 patients. Mean APACHE II scores were significantly increased in patients requiring protracted mechanical ventilation. This suggests that severity of illness scoring may identify those of risk for prolonged intubation.

# Detail Summary Sheet

Date: 1 Oct 94

Protocol Number: C-92-14

Status: Ongoing

Title: Cell Culture Model to Test the Relative Independence of Cancer Cells to Reduced T3 Levels by Comparison to More Normal Cells

Start date:	Estimated completion date:
Principal Investigator: MAJ Kevin Carlin, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Endocrinology	Associate Investigator(s): Isidoro Chapa
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine if reversible hypothyroidism can be induced briefly in euthyroid patients, conceivably normal cells can be induced into a hypometabolic state while the diseased cells continue at their baseline or near baseline metabolic level.

Technical Approach: Cell cultures will be grown from prostate tissue recently removed with TURP by urology and documented prostate cancer present by pathological exam.

Progress: The data has been written up and submitted for publication which is pending at this time. (Presented in abstract already)



# Detail Summary Sheet

Date: 25 Oct 94                      Protocol Number: C-92-18                      Status: Ongoing

Title: The Natural History of HIV Infection and Disease in United States Military Beneficiaries

Start date: 1 Feb 92	Estimated completion date:
Principal Investigator: MAJ J. William Kelly, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Infectious Disease	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 131  
 Total number of subjects enrolled to date: 184  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): a) To systematically document the natural disease progression in individuals with HIV infections in a general military population. b) To form a study cohort which will be eligible for participation in treatment protocols and for other studies related to specific aspects of the descriptive elements (natural history) of HIV infection.

Technical Approach: Proposal is to organize information in a data base now being routinely collected on HIV patients into a data base, henceforth referred to as the BAMC Natural History Study, in such a way that more scientifically valid information will be forthcoming and safeguards to patient confidentiality are met.

Progress: 184 BAMC patients have been enrolled to date. This protocol is a component of an overall Tri-service natural history study which now has a registry of over 1800 patients.

# Detail Summary Sheet

Date: 1 Oct 94 Protocol Number: C-92-23 Status: Completed

Title: An Open-Label Multi-Investigator Comparative Study of the Safety and Efficacy of Cefipime and Ceftazidime in the Treatment of Hospitalized Patients with Septicemia

Start date:	Estimated completion date:
Principal Investigator: MAJ John H. Schrank, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Infectious Disease	Associate Investigator(s): COL C. Kenneth McAllister, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 30  
 Total number of subjects enrolled to date: 30  
 Periodic review date: Review results:

Objective(s): To evaluate the efficacy of cefepime (2 g q8h) versus ceftazidime (2 g q8h) in the treatment of patients with clinically and bacteriologically documented bacterial septicemia with or without a confirmed site of local infection. Emphasis is placed on the isolation of pathogen(s) from 2 or more sets of pretreatment blood cultures from patients with suspected septicemia. An additional objective is to achieve further experience concerning the safety and tolerance of cefepime compared to ceftazidime, with both agents administered as a 6-g total daily dose in patients with serious, life-threatening septicemia.

Technical Approach: This is an open-label, randomized, comparative, multi-center evaluation of the safety and efficacy of cefepime versus ceftazidime in the treatment of clinically and bacteriologically documented septicemia, with or without a confirmed site of local infection. Patients who meet the inclusion and pass the exclusion criteria will be randomly assigned to receive either cefepime or ceftazidime (1:1 randomization, cefepime:ceftazidime). It is anticipated that approximately 1000 patients (100 evaluable per treatment group) will be enrolled at 30 to 40 selected sites over a period approximately

C-92-23 (continued)

12 months.

Progress: Project completed. Study results are being analyzed and will be published.

# Detail Summary Sheet

Date: 4 Oct 94	Protocol Number: C-92-25	Status: Completed
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Title: Randomized, Double-Blind Study Comparing Medroxyprogesterone Acetate and Placebo in Cancer Cachexia

Start date: Apr 92	Estimated completion date: Dec 94
Principal Investigator: CPT Karen J. Bowen, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s): LTC Timothy J. O'Rourke, MC
Key Words: Cachexia, Medroxy-progesterone, Cancer	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4  
 Total number of subjects enrolled to date: 10  
 Periodic review date: 31 Dec 93 Review results: \_\_\_\_\_

Objective(s): 1) To evaluate the effect of medroxyprogesterone acetate (MPA) vs. placebo in patients with cancer and weight loss. 2) A secondary goal is to evaluate the quality of life in patients receiving MPA.

Technical Approach: Ninety (90) patients, 18 years of age and older, with unresectable or recurrent solid tumors will be randomized to one of two arms matching patients by performance status, ongoing chemotherapy, and tumor type. Eligible patients will be placed on one arm of the study to receive either MPA or placebo. Patients receiving MP will be treated with a dose of 400 mg given orally once daily. Treatment will continue indefinitely unless patients are removed from the study at the discretion of the treating physician.

Progress: Eleven patients are deceased. Study is closed due to slow patient accrual.

# Detail Summary Sheet

Date: 4 Oct 94                      Protocol Number: C-92-30                      Status: Ongoing

Title: Regression of Metaplastic Esophageal Epithelium With Omeprazole

Start date: Feb 92	Estimated completion date: Jan 95
Principal Investigator: MAJ Richard Shaffer, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s): LTC Shailesh Kadakia, MC MAJ John G. Carrougner, MC
Key Words:	
Cumulative MEDCASE cost: \$1000	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 21  
Total number of subjects enrolled to date: 6  
Periodic review date: Mar 93                      Review results: \_\_\_\_\_

Objective(s): To determine if regression of metaplastic esophageal epithelium (Barrett's esophagus) can be induced by utilizing a hydrogen proton pump inhibitor (Omeprazole) to create an achlorhydric environment.

Technical Approach: 80 patients will be enrolled. Age, sex, duration of disease and prior therapy will be noted for demographic data. Primary exclusion criteria will be due to an indeterminant gastro-esophageal junction by direct endoscopic observation. After complete information outlining the requirements for the study, the current FDA status of Omeprazole and other literature regarding long-term usage of Omeprazole, those subjects declining enrollment in the Omeprazole study group will serve as controls (as they are routinely undergoing annual surveillance). Those meeting endoscopic criteria will be randomized to omeprazole or H<sub>2</sub>-blockers.

Progress: Twenty-two patients are enrolled with 18 of 22 reaching the 2 year endpoint of the study. To date, no change has been noted in Barrett's epithelium from baseline measurement at reference tattoo at 3, 9, 15, or 24 months. No complications reported due to the study. Project continuation of the study an additional 1 1/2 years to bring all study patients to the 2 year endpoint.

# Detail Summary Sheet

Date: 25 Aug 94                      Protocol Number: C-92-34                      Status: Completed

Title: Phase I Trial of RP60475 Administered as a One-Half Hour Infusion Every 21 Days

Start date: 29 Jan 92	Estimated completion date: 15 May 93
Principal Investigator: MAJ Howard A. Burris, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 9  
 Total number of subjects enrolled to date: 9  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To determine the maximum tolerated dose of RP60475 administered as a 1/2 hour infusion given every 21 days. 2) To determine the qualitative and quantitative toxicities of RP60475 on this schedule. 3) To determine the recommended dose for RP60475 on this schedule in Phase II trials. 4) To characterize the pharmacokinetics/pharmacodynamics of RP60475. 5) To collect information about antitumor effects of RP60475.

Technical Approach: This is a rising dose, open-label, Phase I study of RP 60475 utilizing a dosage regimen of a 1/2 hour intravenous infusion every 3 weeks. Standard methodology for a Phase I oncology study will be utilized. The dosage levels to be studied are 12, 24, 40, 60, 84, 110, 130, 156, and 180 mg/m<sup>2</sup>.

Progress: A maximally tolerated dose of 425 mg/m<sup>2</sup> was achieved, with the dose limiting toxicity being hepatotoxicity (transaminasemia). Alternative schedules are being explored at other institutions to achieve greater dose intensity. A manuscript has been prepared and is being submitted to the Journal of Clinical Oncology.

# Detail Summary Sheet

Date: 25 Aug 94                      Protocol Number: C-92-38                      Status: Terminated

Title: Pharmacokinetic Guided Phase I Evaluation of 7U85 Mesylate  
Administered Intravenously as a Two-Hour Infusion Every 28 Days

Start date:	Estimated completion date:
Principal Investigator: MAJ Howard A. Burris II, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2  
Total number of subjects enrolled to date: 2  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To determine the maximum tolerated dose (MTD) of 7U85 mesylate when administered intravenously, as a two-hour infusion once every 28 days. 2) To define qualitatively and quantitatively the toxicities of 7U85 mesylate when administered as a single dose every 28 days. 3) To apply a pharmacokinetic guided dose escalation procedure, in which AUC is measured, in order to decrease numbers of patients to achieve the MTD. 4) To determine the basic pharmacokinetics of 7U85 mesylate by study of plasma and urinary concentrations of the agent in patients. 5) To collect information about the antitumor effects of 7U85 mesylate.

Technical Approach: This is a rising dose, open-label Phase I study of 7U85 administered as a two hour infusion every 21-28 days. Standard methodology for a Phase I oncology study will be utilized. This protocol was amended and revised to decrease the study dose of drug and to allow a more conservative dose escalation scale. G-CSF was added to the regimen to prevent prolonged neutropenia.

Progress: A limited number of patients were enrolled on this trial as the sponsor elected to not pursue this schedule of administration. Future directions with this agent are not clearly defined at this time.

# Detail Summary Sheet

Date: 1 Oct 94

Protocol Number: C-92-41

Status: Ongoing

Title: Quantification of T3 Receptors in Human Cancer Tissue Compared to the Tissue from the Clear Margin of the Same Surgical Specimen

Start date:	Estimated completion date:
Principal Investigator: Kevin Carlin, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Endocrinology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): Patients whose medical care has already dictated a surgical procedure for diagnosis and/or therapy of a possible cancer will be considered as a possible candidate to enter the study. There will be no exclusion factors. The only impact to patients for participation is the tissue that was to be removed any will undergo additional analysis.

Technical Approach: Patients with known or strongly suspected cancers who are undergoing surgery for diagnosis and/or therapy will have postop examination and testing of a representative sample of their mass and the clear margin. Samples will have their T3 receptors quantified by a previously utilized, well documented method. If the hypothesis is correct, there should be a higher percentage of T3 receptors in the clear margin than in the cancer cells.

Progress: Doctor Merrill is having difficulty getting T<sub>3</sub> assay to work.



# Detail Summary Sheet

Date: 3 Oct 94                      Protocol Number: C-92-53                      Status: Ongoing

Title: Core Protocol for HIV Developmental Diagnostic (Adult).

Start date:	Estimated completion date:
Principal Investigator: MAJ J. William Kelly, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Infectious Disease	Associate Investigator(s): Donald S. Burke, COL, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 90  
 Total number of subjects enrolled to date: 90  
 Periodic review date: 22 Mar 93                      Review results:

Objective(s): a) To develop and evaluate new and/or improved laboratory methods for establishing the diagnosis of HIV, and to correlate detectable HIV virus, HIV antigen, and/or HIV nucleic acid in blood with clinical status. b) To develop and evaluate new and/or improved laboratory methods for assessing the virus-specific immune response to HIV infection, and to correlate detection of virus-specific antibody or cell mediated immune responses with clinical status.

Technical Approach: Under this protocol, the patient will be asked to give informed consent that his/her blood can be used for the general purpose of development and evaluation of virologic and immunologic techniques, and that his/her clinical records can be reviewed in order to correlate test results with his/her clinical condition. Solicitation of patients will be done in the Infectious Disease Clinic by a protocol manager on the Infectious Disease Clinic.

Progress: Approximately 146 subjects have been enrolled to date. Serum and cells from these patients have been banked for use in development of diagnostic methods.

# Detail Summary Sheet

Date: 15 Aug 94 Protocol Number: C-92-64 Status: Terminated

Title: A Phase I Trial of OKT3 (Anti-CD3) Monoclonal Antibody After High Dose Chemotherapy and Autologous Bone Marrow Transplantation in Patients with Breast Cancer.

Start date:	Estimated completion date:
Principal Investigator: Svetislava J. Vukelja, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s): W. Jeff Baker, MAJ, MC Barbara Reeb, DAC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To determine the toxicities as well as the maximum tolerated dose of OKT3 antibody given after high-dose chemotherapy and autologous bone marrow transplantation in patients with breast cancer. 2) To determine the effect of OKT3 antibody on lymphocyte reconstitution postgrafting compared to lymphocyte reconstitution that occurs without administration of OKT3 after tandem high-dose chemotherapy and autologous bone marrow transplantation in patients with breast cancer. 3) If tumors are easily assessable for biopsy, determination at the results of cytotoxicity assays on tumor cells using OKT3 stimulated as well as unstimulated peripheral blood lymphocytes from the patients.

Technical Approach: Study has not started. We do not have HSC approval. This protocol should be closed since it has never opened.

# Detail Summary Sheet

Date: 25 Aug 94 Protocol Number: C-92-65 Status: Completed

Title: A Phase I Trial Of Toremifene and Doxorubicin in Patients with Advanced Malignancies

Start date: 13 Apr 92	Estimated completion date: 1 Jan 94
Principal Investigator: Howard A. Burris III, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 13  
 Periodic review date: Review results:

Objective(s): 1) To determine the maximally protective dose (i.e., that dose associated with clinically acceptable, predictable, and reversible toxicity) of toremifene when administered concomitantly. 2) To determine plasma pharmacokinetics of toremifene and doxorubicin when administered concomitantly. 3) To determine the chemosensitizing activity of toremifene when administered with doxorubicin. 4) To assay tissue samples for toremifene concentrations, and expression of MDR (multi-drug resistance) and associated gene-products pre- and post-toremifene treatment. 5) To evaluate for clinical evidence of MDR reversal by restoration of chemotherapeutic responsiveness in doxorubicin refractory cancer patient. 6) To determine the recommended dose for toremifene when given with doxorubicin (60 mg/m<sup>2</sup>IV every 21 days) for Phase II trials.

Technical Approach: Patients with advanced or refractory solid tumors will be treated at each dose level of toremifene. Two patients will have been previously treated with doxorubicin, and two patients will not have been previously treated with doxorubicin. One patient from each of these 2 groups (prior or no prior doxorubicin) must be followed for 3 weeks with the second patient followed for a minimum of one week prior to proceeding to the next dose level.

Progress: This trial has been completed with a total of 34 patients enrolled. no objective responses were observed. Prolonged neutropenia was noted with a Toremifene dose of 40 mg/day with 75 mg/m<sup>2</sup> of Doxorubicin. A manuscript is in preparation.

# Detail Summary Sheet

Date: 3 Aug 94                      Protocol Number: C-92-68                      Status: Ongoing

Title: Prophylactic Low Dose Coumadin and Antiplatelet Therapy in the Nephrotic Syndrome Secondary to Membranous Nephropathy.

Start date: Jul 92	Estimated completion date: Jun 97
Principal Investigator: Gail L. Seiken, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Nephrology	Associate Investigator(s):
Key Words: Nephrotic Syndrome Membranous nephropathy	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Jan 93                      Review results: N/A

Objective(s): 1) To prospectively examine the incidence of thrombotic events in patients with nephrotic syndrome secondary to membranous nephropathy. 2) To prospectively evaluate the role of low dose coumadin and antiplatelet therapy in the prevention of thrombotic complication of nephrotic syndrome secondary to membranous nephropathy. 3) To prospectively evaluate the benefit of anticoagulation in patients with documented thrombosis associated with the nephrotic syndrome of membranous nephropathy.

Technical Approach: This is a prospective, randomized study designed to evaluate the incidence of thromboembolic complications in patients with idiopathic membranous glomerulopathy, and the potential role for prophylactic low dose coumadin and antiplatelet therapy in the prevention of these complications.

Progress: No patients have been entered into study thus far. All information is current. Study remains ongoing for patient accrual.

# Detail Summary Sheet

Date: 1 Oct 94                      Protocol Number: C-92-69                      Status: Terminated

Title: A Double-Blind, Randomized, Comparative, Multicenter Study of CI-983 in the Treatment of Community-Acquired Bacterial Pneumonia

Start date:	Estimated completion date:
Principal Investigator: MAJ Gregg T. Anders, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Pulmonary Disease	Associate Investigator(s): CPT Dan Loube, MC
Key Words:	
Cumulative MEDCASE cost: 0	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To evaluate the efficacy and safety of two dosage regimens of CI-983 versus cefaclor in the treatment of patients with community-acquired bacterial pneumonia.

Technical Approach: Double-blind trial comparing one antibiotic to another in community-acquired pneumonia.

Progress: This protocol is officially closed. Documentation was sent to sponsor and FDA. No patients were entered on this study.

# Detail Summary Sheet

Date: 4 Oct 94                      Protocol Number: C-92-70                      Status: Ongoing

Title: The Prevalence of Colonic Neoplasms in Patients with Known Breast Adenocarcinoma

Start date:	Estimated completion date:
Principal Investigator: MAJ John Carrougher, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s): CPT Karen Bowen, MC LTC Shailesh Kadakia, MC CPT Richard Shaffer, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 30  
 Total number of subjects enrolled to date: 38  
 Periodic review date: 15 Oct 92      Review results: \_\_\_\_\_

Objective(s): The purpose of this study is to determine the prevalence of colonic neoplasms in female patients with breast adenocarcinoma. We wish to determine if colonic neoplasms occur in greater frequency in patients with breast carcinoma than in a similarly matched control population. The information obtained from this study should be used to establish guidelines on colonoscopic surveillance in patients with breast cancer.

Technical Approach: Patient population will consist of all patients currently receiving care for breast adenocarcinoma in the oncology clinic at Brooke Army Medical Center. A letter will be sent to each patient soliciting participation. All participants will undergo colon screening to be accomplished by colonoscopy.

Progress: To date, a total of 72 patients have been enrolled with the study remaining ongoing for patient followup with no data to report.

# Detail Summary Sheet

Date: 15 Aug 94

Protocol Number: C-92-81

Status: Ongoing

Title: The Induction of the Alpha-Delta Sleep Anomaly and Fibromyalgia Symptoms in Normal Subjects: Correlations with Calorimetry and Insulin-like Growth Factor-1 (RENAMED)

Start date:	Estimated completion date:
Principal Investigator: MAJ Steven A. Older, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Rheumatology	Associate Investigator(s): LTC Daniel F. Battafarano, MC Sabri Derman, D.Sc I. Jon Russell, M.D., Ph.D. CPT Eugene Grady, MC
Key Words: fibromyalgia, sleep, Alpha-Delta, calorimetry, Insulin-Like Growth Factor1	
Cumulative MEDCASE cost: None	Estimated cumulative OMA cost: None

Number of subjects enrolled during reporting period: 6  
 Total number of subjects enrolled to date: 15  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To determine if artificial creation of Alpha-Delta sleep anomaly by selective deep sleep deprivation causes the development of fibromyalgia symptoms. 2) To determine if physical conditioning is protective against the development of fibromyalgia symptoms in sleep deprived individuals. 3) To analyze and compare serum levels of Insulin-like Growth Factor-1 in these individuals.

Technical Approach: Involves the evaluation of approximately 24 health civilian and active duty military volunteers between the ages of 18 and 40. These subjects, chosen in random order, will be studied in three separate groups: 1) Six subjects examined but not deprived of sleep (sham group); 2) Six subjects deprived of stage IV sleep (Stage IV group); 3) Twelve subjects deprived of both stages III and IV sleep (Stage III and IV group). Sleep deprived individuals will undergo five nights of monitoring in a sleep laboratory study. Their sleep will be undisturbed on nights #1 and #5 and interrupted by auditory stimulus on nights #2, #3, and #4 in order to achieve appropriate sleep stage deprivation. All subjects will be examined each morning and evening for the presence of tender points which will be measured quantitatively by dolorimetry. Urine and blood will be obtained for measurement of Insulin-like Growth Factor-1. All sleep deprivation subjects



C-92-81 continued)

will undergo calorimetry testing within three weeks of their sleep study.

Progress: Fifteen of the projected 24 subjects have been studied. To date we have demonstrated that overnight pain scores measured by dolorimetry improve in the sham group, deteriorate in the stage III and IV deprivation group, and are intermediate in the stage IV deprivation group. Calorimetry data and Insulin-like Growth Factor analysis have not been correlated. These findings support the hypothesis that a disturbance in delta wave sleep is involved in the pathogenesis of fibromyalgia and show that the effect depends on the magnitude of deprivation. Evaluation of the remaining nine subjects as well as calorimetry and serologic data should be completed by mid-November.

# Detail Summary Sheet

Date: 25 Aug 94 Protocol Number: C-92-83 Status: Completed

Title: A Randomized Phase II/III Study of PIXY321 (GM-CSF/IL-3 S. cerevisiae Fusion Protein) or Placebo in Combination with DHAP as Salvage Therapy for Lymphoma

Start date: 28 Aug 92	Estimated completion date: 1 Jan 94
Principal Investigator: CPT Howard A. Burris III, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s): CPT Karen J. Bowen, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 6  
 Total number of subjects enrolled to date: 13  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To compare the effectiveness of SC PIXY321 to placebo in reducing the serverity of chemotherapy-associated myelosuppression in patients with relapsed or refractory lymphoma treated with DHAP chemotherapy.

Technical Approach: This will be a multi-center, randomized, double blind, phase II/III study in which eligible patients will be randomized to received either 2 cycles of DHAP chemotherapy followed by a fixed dose of SC PIXY321 or 2 cycles DHAP chemotherapy followed by placebo.

Progress: Accrual is complete on this trial with a total of 56 patients enrolled. A dose of 750 mcg/m<sup>2</sup> is the recommended phase II dose of PIXY. Trends toward decreased duration of thrombocytopenia were observed. Phase III trials have been planned utilizing this combination. Results will be presented at the ASH meeting in Dec 94.

# Detail Summary Sheet

Date: 25 Oct 94 Protocol Number: C-92-85 Status: Ongoing

Title: Possible Hormone Manipulations in The Treatment of HIV Infections Using Variations in Cell Culture Medium to Test for Facilitators and Inhibitors from the Hormone Family

Start date:	Estimated completion date:
Principal Investigator: MAJ Kevin Carlin, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Endocrinology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To culture human T cells in a culture medium devoid of human or calf serum. This will allow full knowledge of what actually is necessary to culture T cells.

Technical Approach: Volunteers between ages 18-65 who are not pregnant will donate 10 ml of blood after signing a consent form. This 10 ml of blood will then undergo a process in order to culture normal human T cells. The 10 ml of whole blood will then be spun down to separate red blood cells from white blood cells. The buffy coat containing the white blood cells will then be removed and mononuclear leukocytes obtained via Ficoll-hypaque isopyphic centrifugation.

Progress: Currently undertaking to see effect of Triac/Tetrac thyroid analogues upon HIV replication.

We are now repeating this experiment in larger groups with results to be published if once again, T cells are found to be independent. There are no complications/misadventures with all blood drawn only on subjects who also are part of the project.

# Detail Summary Sheet

Date: 8 Aug 94                      Protocol Number: C-92-88                      Status: Terminated

Title: Validation of a New Doppler-Echo Method for Quantification of Mitral Regurgitation

Start date:	Estimated completion date: Jun 93
Principal Investigator: MAJ David M. Mego, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s): CPT Sheri Y. Nottestad, MC LTC John W. McClure, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 7  
Total number of subjects enrolled to date: 24

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To correlate the mitral regurgitant flow volume as determined by two techniques -- 1) the difference between angiographic and thermodilution stroke volumes at cardiac catheterization, and 2) a newly described method using the product of the mitral regurgitant Doppler color flow jet area and time velocity integral.

Technical Approach: Study will involve fifty patients of age greater than 18 years with mitral regurgitation who are undergoing diagnostic right and left heart cardiac catheterization. These patients will have no other significant regurgitant valvular lesions.

Progress: 17 patients have been enrolled, 13 of whom had technically adequate studies. In this group, good correlations have been established between the angiographic grade of mitral regurgitation and the Doppler color flow jet diameter ( $r=0.84$ ) and Doppler-derived regurgitant volume ( $r=0.797$ ). We continue to enroll 1-2 patients per week. Study completed. 24 patients were enrolled, 18 of whom had technically adequate studies. Using a Spearman rank order  $r=0.833$  for Doppler color flow jet diameter and  $r=0.831$  for Doppler-derived regurgitant volume, has compared with angiographic grading of mitral regurgitation. These results have been presented to the American College of Physicians Army 10th Annual Scientific Meeting. A manuscript is in

preparation.

# Detail Summary Sheet

Date: 5 Aug 94 Protocol Number: C-92-93 Status: Completed

Title: Phase IV Study to Evaluate the Effect of Intravenous of Acute Hospital Admissions for Congestive Heart Failure

Start date:	Estimated completion date:
Principal Investigator: MAJ Landon Wellford, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4  
 Total number of subjects enrolled to date: 5  
 Periodic review date: Review results:

Objective(s): To evaluate the efficacy, safety, outcome, and length of stay for patients receiving intravenous milrinone compared to patients receiving dobutamine in the course of their hospital admissions for acute exacerbations of chronic heart failure.

Technical Approach: This is an open, parallel, randomized study of intravenous milrinone compared to dobutamine in patients who are admitted to the hospital with acute exacerbations of chronic heart failure. Study will include 125 cardiologists who will each treat a minimum of 4 patients for a total of approximately 500 patients. A three-month time period is allotted for the enrollment of the 4 patients.

Progress: We enrolled four patients as planned. All data collected and tabulated. All forms have been turned into data collection center. Study closed and results pending.

# Detail Summary Sheet

Date: 7 Nov 94

Protocol Number: C-92-94

Status: Ongoing

Title: Colon Carcinogenesis: Modulation by Dietary Intervention

Start date:	Estimated completion date:
Principal Investigator: LTC Shailesh Kadakia, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 58

Total number of subjects enrolled to date:

Periodic review date: Review results:

Objective(s): 1) To assess the modulation of cellular proliferation in colonic crypts (a biomarker of colon cancer risk) by dietary supplementation with cellulose in patients identified at higher than normal risk of developing malignant colon cancer. 2) To determine if longer term dietary intervention (1 year or more) of the same supplements will result in a significant reduction in the recurrence of adenomatous polyps in the colon.

Technical Approach: Study will be conducted using a prospective randomized control trial. Two dependent variables will be measured: 1) proliferative zone height (PZH), the biomarker previously discussed in the Background and Significance Section and 2) recurrence rate of sporadic adenomatous polyps. The dependent variable, cellulose supplementation will be composed of three levels: 0, 15, and 25 grams/day above normal baseline intake level.

Progress: Data collection is continuing and there are no reportable results at this time.

# Detail Summary Sheet

Date: 3 Aug 94

Protocol Number: C-92-97

Status: Ongoing

Title: Prospective Study of Clinical Efficacy of Two Formulations of Verapamil in Hypertensive Patients

Start date:	Estimated completion date:
Principal Investigator: MAJ J. Grant Barr, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Nephrology	Associate Investigator(s): MAJ William Wright, MC
Key Words: Hypotension Calcium Channel Blocker	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 0

Periodic review date: Review results:

Objective(s): To determine whether there are differences in efficacy, duration of action or side effects profiles of two different sustained release preparations of the calcium channel blocker. verapamil. The hypothesis is that there are no clinically significant differences in the two products and that their duration of action is similar.

Technical Approach: Prior to beginning of experimental phase of the study, patients will have objective and subjective data collected. Patients will not be on any calcium channel blocker during this period however, all medications they are taking will be recorded. Physical examination will include recording of blood pressure and informed consent will be obtained.

Progress: Principal investigator has PCS'd. No one in Nephrology Service will take over this study. The Associate Investigator, LTC William Wright is TDY at another site. Study should be placed on hold until Dr. Wright's return and a determination is made as to whether he wishes to continue this study.



# Detail Summary Sheet

Date: 1 Oct 94

Protocol Number: C-92-98

Status: Ongoing

Title: Possible Etiology for Euthyroid Sick Syndrome

Start date:	Estimated completion date:
Principal Investigator: MAJ Kevin Carlin, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Endocrinology	Associate Investigator(s): Gerald Merrill, Ph.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): Patients admitted to Brooke Army Medical Center (BAMC) who are seriously ill will potentially become candidates in the study. Judgement will be made by TRISS and APACHE III evaluation (an independent established method of objectively scoring patients) within 12 hours of admission to BAMC surgical or medical ICU by the staff physician involved in the study.

Technical Approach: Thyroid hormone levels and Triac/Tetrac levels will be tested in ICU patients at admission, as well as at 3 to 4 days and 2 weeks after admission. Subjects will vary as to their primary problem but all will be significantly ill. Analysis will be done to see if their clinical course and thyroid function tests correlate with Triac/Tetrac levels.

Progress: Dr. Merrill of clinical Investigation continues to attempt to isolate triac/tetrac.

# Detailed Summary Sheet

Date: 14 Sep 94

Protocol Number: C-93-01

Status: Ongoing

Title: Does Cholecystokinin (CCK) Prevent Gallbladder Sludge or Gallstone Formation in Patients Receiving Parenteral Nutrition? A Randomized Double-Blind Trial

Start date: 14 Oct 92	Estimated completion date:
Principal Investigator: Shailesh C. Kadakia, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s): Rashmikan B. Shah, M.D. Susan W. Wilson, M.S., R.D., L.P.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To compare the efficacy of cholecystokinin in preventing or reducing the incidence of gallbladder sludge and/or cholelithiasis formation in patients receiving total parenteral nutrition (TPN). The incidence of sludge and gallstones formation in the gallbladder will be determined in patients receiving either intravenous cholecystokinin or placebo.

Technical Approach: All patients started on TPN will be invited to participate. The presence of gallbladder sludge and gallstone will be evaluated by standard ultrasound (US) technique. Appropriate images will be obtained for each study to record the findings for later review.

Progress: As of 14 Sep 94, one subject has been entered in this study and has undergone base line ultrasound evaluation followed by CCK stimulation of the gallbladder. Patients will continue to be enrolled as well as normal control subjects.

# Detail Summary Sheet

Date: 14 Sep 94 Protocol Number: C-93-02 Status: Ongoing

Title: Aspirin or Sulindac Use and the Prevalence of Distal Colonic Adenomas

Start date: Oct 92	Estimated completion date:
Principal Investigator: Carl S. Wroblewski, M.D.	Facility: Darnall Army Hospital & Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine whether a statistically significant difference exists in the prevalence of distal colonic adenomas by fiberoptic flexible sigmoidoscopy of distal colonic adenomas by fiberoptic flexible sigmoidoscopy (FFS) in a population of aspirin or NSAID users and nonusers.

Technical Approach: Eligible patients will have a FFS performed by physicians in either the Internal Medicine or Gastroenterology Clinics after proper counselling. A colon cleansing preparation consisting of two Fleet's one hour prior to the examination will be administered.

Progress: As of 14 Sep 94, we are continuing to have patients complete the questionnaire prior to undergoing flexible sigmoidoscopy. The questionnaires are collected at the end of the examination and filed, the data has not been analyzed or reviewed. The study is ongoing and data will be analyzed or reviewed. The study is ongoing and data will be analyzed after about 12 to 24 months.

# Detail Summary Sheet

Date: 15 Aug 94                      Protocol Number: C-93-03                      Status: Ongoing

Title: 5-Fluorouracil Iontophoretic Therapy for Bowenoid Conditions

Start date: 26 Oct 92	Estimated completion date:
Principal Investigator: Martha L. McCollough, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Dermatology	Associate Investigator(s): Lawrence Anderson, M.D. William Grabski, M.D. Padman Menon, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 10  
 Total number of subjects enrolled to date: 10  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine if the iontophoresis of 5-fluorouracil (5-FU) is an effective treatment for Bowen's disease and/or bowenoid actinic keratoses.

Technical Approach: As outlined in the protocol.

Progress: Ten patients with 12 lesions have been treated with iontophoresis of 5-FU. No complications noted and the treatment was well tolerated by all patients. No patients have had the excision performed which will occur 3 months after the final treatment. We are continuing to enroll patients in the study. No funding requirement for FY95.

# Detail Summary Sheet

Date: 1 Oct 94      Protocol Number: C-93-05      Status: Ongoing

Title: A Comparison Study of the Prevention of Acute Aspirin Induced Gastroduodenal Injury with Omeprazole Versus Misoprostol

Start date: Mar 93	Estimated completion date: Jan 94
Principal Investigator: Timothy Pfanner, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s): R. Shaffer, M.D. J. Carrougher, M.D. S. Kadakia, M.D.
Key Words:	
Cumulative MEDCASE cost: 0	Estimated cumulative OMA cost: 0

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: 24  
 Periodic review date: 1 Dec      Review results: See below

Objective(s): To compare the effect of omeprazole versus misoprostol in the prevention of aspirin induced gastroduodenal mucosal damage in healthy volunteers.

Technical Approach: As outlined the study protocol.

Progress: Twenty-four patients have completed the study to date with Misoprostol preventing erosions and ulcerations vs placebo and Omeprazole showing no significant differences vs placebo. Approximately 40 more patients are required for completion of the study. Will require 1-2 years for completion; study ongoing.

# Detail Summary Sheet

Date: 7 Nov 94 Protocol Number: C-93-06 Status: Ongoing

Title: Aspirin or Sulindac Use and the Prevalence of Distal Colonic Adenomas

Start date: Oct 92	Estimated completion date:
Principal Investigator: Shailesh C. Kadakia, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s): Shailesh C. Kadakia, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): The purpose of this study is to determine whether a statistically significant difference exists in the prevalence of distal colonic adenomas by fiberoptic flexible sigmoidoscopy (FFS) in a population of aspirin or NSAID users and nonusers.

Technical Approach: Patients undergoing a FFS in either the Internal Medicine Clinic at Darnall Army Community Hospital or the Gastroenterology Clinic at BAMC will be eligible for the study. Detailed exclusion data, etc, in protocol.

Progress: Since the approval of the protocol in Oct 92, most patients undergoing FFS at GI Svc have been handed out a questionnaire which is collected soon after the FFS is completed. Questionnaires have not been analyzed at the present time. Many of the questions have not been appropriately answered by the patients and will require telephone calls in order to obtain detailed information concerning those questions. We continue to collect the questionnaires in the same fashion. As of 14 Sep 1994, we are continuing to have patients complete the questionnaire prior to undergoing flexible sigmoidoscopy. The questionnaires are collected at the end of the examination and filed, the data has not been analyzed or reviewed. The study is ongoing and data will be analyzed after about 12 to 24 months.

# Detail Summary Sheet

Date: 4 Oct 94                      Protocol Number: C-93-08                      Status: Ongoing

Title: Endosonoscopic Evaluation of Helicobacter Pylori Associated Gastritis

Start date: 2 Nov 92	Estimated completion date:
Principal Investigator: John G. Carrougher, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s): Shailesh Kadakia, M.D. Richard T. Shaffer, M.D. Michael D. Redwine, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: No significant findings

Objective(s): To determine if a sonographic pattern can be demonstrated in the gastric mucosa in patients with H. pylori associated gastritis. This information can help define the condition of H pylori gastritis and may assist the physician in the diagnostic difficulties seen with gastric wall abnormalities.

Technical Approach: The patient population will include all patients discovered to have H pylori infections as demonstrated by histology and/or urease test (clotest) during routine evaluation by the Gastroenterology Svc. The patients will then undergo endosonography followed by CT scan of the stomach wall. The EUS will be performed by the authors. The gastric wall will be examined using the UM3 endosonoscope from Olympus at frequencies of 7.5 and 15 MHZ. The gastric wall will be photographed in several areas during the EUS. CT scans will be photographed in several areas during the EUS. CT scans will be performed per routine of the radiology dept. Attempts will be made to assure adequate distention of the stomach during the CT scans and will be supervised by the radiologic staff. The radiology staff will be blinded to the results of the EUS. Gastric wall thickness will be measured by both modalities. All abnormal findings will be recorded. Patients may be collected from an preexisting protocol and will be studied prior to any antibiotic, or bismuth treatment.

Progress: No new subjects have been enrolled in the last 6 months with the protocol presently inactive and will likely be discontinued if no new subjects can be enrolled over the next 6 months.

# Detail Summary Sheet

Date: 4 Oct 94                      Protocol Number: C-93-12                      Status: Ongoing

Title: ASGE Survey: Anticoagulation and GI Endoscopy

Start date: 3 Nov 93	Estimated completion date:
Principal Investigator: Carlos E. Angueira, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s): Shailesh C. Kadakia, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2,500 surveys  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To survey the practices of randomly selected gastroenterologists throughout the country regarding patients on oral anticoagulation or antiplatelet therapy and the way in which these medications should be adjusted prior to and following gastrointestinal endoscopy.

Technical Approach: Questionnaires addressing the management of patient on oral anticoagulants, antiplatelet therapy and NSAIDs in the periendoscopy period and strategies in dosage adjustments of these agents will be sent to approximately 1200 randomly selected members of the American Society of Gastrointestinal Endoscopy (ASGE) as well as the directors of all the gastroenterology training programs throughout the country. Reminder letters will be sent 30 and 60 days after the questionnaires to ensure the highest rate of return possible. These questionnaires will then be analyzed with a statistical program to establish recommendations based on the consensus of the obtained responses.

Progress: Approximately 2500 surveys have been received. Data is being entered in computer for analysis.



# Detail Summary Sheet

Date: 13 Oct 94      Protocol Number: C-93-18      Status: Ongoing

Title: Monokine Induction in Patients Infected with Coccidioides Immitis

Start date: 16 Nov 92	Estimated completion date:
Principal Investigator: David P. Dooley, M.D.	Facility: SA Chest Hosp; WHMC Brooke Army Medical Center, Texas
Department/Service: Medicine/Infectious Disease	Associate Investigator(s): Rebecca Cox, Ph.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 14  
Total number of subjects enrolled to date: 12: BAMC; 40: SASCH

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine whether infection with the fungus Coccidioides immitis causes an increased production of the monokines tumor necrosis factor- $\alpha$  (TNF- $\alpha$ ), interleukin-1 beta (IL-1B), and interleukin 6 (IL-6) in patients with coccidioidomycosis. Specific aims include the comparison of the in vitro monokine responses of blood monocytes from six study groups: patients with acute (primary) pulmonary coccidioidomycosis; patients with chronic, progressive pulmonary coccidioidomycosis; patients with disseminated coccidioidomycosis; patients with previously diagnosed but inactive coccidioidomycosis; and healthy, spherulin skin-test positive and skin-test negative controls.

Technical Approach: Description of subjects/controls; criteria for inclusion/exclusion; experimental design/methods; data collection; statistical analysis and specifics outlined in protocol.

Progress: Monokine production assays are as published in the attached manuscript. Initial data for IFN- $\gamma$  production from selected cell lines (defined by BAMC FACS, Dr. Lopez/Mr. Ferguson) are seen in appendix 1. Despite excellent fractionation by the magnetic bead technique, a clean definition of IFN- $\gamma$  production from selected cell types has not yet been seen, although the numbers of adequate assays (CD experiments #8-10, with adequate on A control stimulation) are few. Our main difficulty in this line of investigation has been trade-offs between viable, bioactive cells and an

adequate purification of same. Additional studies are underway. Basic differences between the viabilities of live spherules in control (incubation with no cellular components) and total PBMC preparations have been adequately defined (appendix 2). However, clean separations between the abilities of fractionated cells in the killing of live spherules have not yet adequately been performed to our satisfaction. The main difficulties with this line of investigation have been, as per (2) above, the maintenance of cell viability after magnetic bead fractionation, as well as continuing suboptimal performance of both assay procedures currently used to determine spherule viability (CFU counts and labelled leucine incorporation). Despite these difficulties, additional studies are underway, as ultimately a definition of optimal killing of live spherules may have the greatest implications for therapeutic intervention. Cytokine mRNA determinations using RT-PCR of stimulated peripheral blood mononuclear cells isolated from normal donors have been optimized since these gels were run). Initial differences between cytokine patterns demonstrated by cells isolated from skin test-negative and -positive donors appear to be seen. The PCR to measure TNF mRNA has just been optimized (see TB report). With these assays for T-cell responses (esp. TH<sub>1</sub> and TH<sub>2</sub> responses) and monocyte/macrophage responses ready, studies are immediately pending on in situ lung cytokine profiles (one lung fragment destroyed by C. immitis, obtained from a State Chest hospital patient, is frozen and ready). No complications, misadventures, or adverse reactions have occurred as the result of these human studies.

\*Across the three participating institutions, 52 subjects were enrolled during the reporting period; 73 subjects have been enrolled to date.

# Detail Summary Sheet

Date: 4 Oct 94                      Protocol Number: C-93-19                      Status: Ongoing

Title: An Open Protocol for the Use of Agrelin (Anagrelide) for Patients with Thrombocythemia

Start date: 9 Dec 92	Estimated completion date:
Principal Investigator: Timothy O'Rourke, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 1  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To assess the safety and efficacy of Anagrelide in patients suffering from thrombocythemia of various etiologies.

Technical Approach: Inclusion/exclusion criteria; concomitant medications; drug supplies; screening and initial treatment along with other specifics given in protocol.

Progress: One patient continues on study with no ill effects.

# Detail Summary Sheet

Date: 3 Oct 94      Protocol Number: C-93-24      Status: Ongoing

Title: Comparison of the Effects of Nifedipine and Isradipine on Urinary Albumin Excretion and blood Pressure in Patients with Type Two Diabetes, Hypertension and Proteinuria

Start date: 4 Jan 93	Estimated completion date:
Principal Investigator: Kevin C. Abbott, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Nephrology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 9  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): This trial will evaluate the effects of isradipine and a sustained release formulation of nifedipine, Procardia XL<sup>TM</sup>, on arterial pressure and renal function. Renal function will be determined by twenty-four urine collections for creatinine clearance, fractional excretion of sodium, albumin and protein excretion.

Technical Approach: Subjects with type II diabetes with mild to moderate hypertension (defined in protocol) and urinary protein excretion of greater than one gram per twenty - four hours will be enrolled in the study. Age for eligibility will be 45 years or greater.

Progress: Principal Investigator has been deployed. Protocol status is unknown.

# Detail Summary Sheet

Date: 3 Oct 94      Protocol Number: C-93-25      Status: Completed

Title: A Double-Blind Comparison of the Efficacy and Safety of Oral Granisetron (1 mg bid) with Oral Prochlorperazine (10 mg bid) in Preventing Nausea and Emesis in Patients receiving Moderately Emetogenic Chemotherapy

Start date: 7 Jan 93	Estimated completion date: 8 Sep 93
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 6  
 Total number of subjects enrolled to date: 6  
 Periodic review date: 31 Dec 93      Review results: Closed

Objective(s): To compare the efficacy of oral granisetron 1 mg bid with oral prochlorperazine (10 mg bid) mg over 24 hours and 7 days, in preventing nausea and emesis in patients receiving moderately emetogenic chemotherapy.

Technical Approach: Treatment regimen, chemotherapy, primary/secondary efficacy parameters, safety assessments and specifics given in protocol

Progress: A total of six patients were treated on this double-blind protocol, meeting our obligations to this multi-institutional study. The results have not yet been unblinded, so final comparison cannot be made. Overall, both treatment groups did reasonably well in the study.

# Detail Summary Sheet

Date: 15 Sep 94 Protocol Number: C-93-26 Status: Ongoing

Title: Effect of Intravenous Erythromycin on Gastric Emptying in Patients with Anorexia Nervosa or Bulimia

Start date: 2 Nov 92	Estimated completion date:
Principal Investigator: Shailesh C. Kadakia, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s): Neil Katz, M.D. Susan E. McManis, M.D., WHMC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 7  
 Total number of subjects enrolled to date: 7  
 Periodic review date: Review results:

Objective(s): To evaluate the efficacy of intravenous erythromycin on gastric emptying in patients with anorexia nervosa or bulimia. The radionuclide assessed gastric emptying of a standard meal will be performed as baseline in these patients on empty into the study. On a later day, the patients will undergo repeat gastric emptying study 30 minutes after receiving a single dose of 250 mg of intravenous erythromycin. These studies will be compared to the baseline study to determine the beneficial effect of erythromycin on the gastric emptying.

Technical approach: The importance of this project will be to demonstrate that erythromycin enhances gastric emptying in patients with anorexia and bulimia nervosa who have delayed gastric emptying. Since symptoms such as nausea, vomiting, abdominal pain, and early satiety may occur in these patients due to delayed gastric emptying, demonstration of faster gastric emptying after administration of erythromycin may provide therapeutic options in these patients.

Progress: Between 1 Dec 93 and 14 Sep 94 no additional patients have been entered in the study. The study is ongoing at the present time. The data analyzed is not different than previously reported since there are no additional patients in the study.

# Detail Summary Sheet

Date: 25 Aug 94      Protocol Number: C-93-27      Status: Completed

Title: A Randomized Phase I Trial of VP-16 with or without GM-CSF for the Treatment of Advanced Cancer

Start date: 4 Jan 93	Estimated completion date: Feb 94
Principal Investigator: Howard A. Burris, M.D.	Facility: UTHSCSA Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Daniel D. VonHoff, M.D. Mace Rothenberg, M.D. Gladys I. Rodriguez, M.D. John Eckardt, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 8  
 Periodic review date: 31 Dec 93      Review results: Continue

Objective(s): To estimate the maximally tolerated dosage, and frequency and types of toxicities of etoposide when combined with rHuGM-CSF in patients with advanced malignancy. To determine which schedule of administration of rHuGM-CSF (prior to or during etoposide treatment) is superior in terms of the greater amount of etoposide delivered. To determine a recommended dosage and schedule for etoposide +/- rHuGM-CSF to be used in phase II trials. To document any responses which may be observed during treatment with the combined regimen. To evaluate the effects of rHuGM-CSF on the blood levels of etoposide administered orally.

Technical Approach: Background/rationale, patient eligibility, treatment plan, dosage and specifics in protocol.

Progress: Accrual has been completed and an abstract and presentation was made at the AACR meeting in April 94. Results revealed improved tolerability with GM-CSF, and phase II trial are being planned.

# Detail Summary Sheet

Date: 25 Aug 94 Protocol Number: C-93-28 Status: Ongoing

Title: Phase II Study of Brief Intravenous Adozelesin Infusion in Previously Untreated Extensive Small-Cell Lung Cancer

Start date: 29 Jan 93	Estimated completion date: May 94
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 1  
 Periodic review date: 31 Dec 93 Review results: Continue

Objective(s): To assess whether adozelesin given as a monthly intravenous infusion produces objective clinical responses in adult patients with previously untreated extensive small cell lung cancer. To determine the qualitative and quantitative toxicity and reversibility of toxicity of adozelesin administered in this fashion.

Technical Approach: This trial will be an open label, non-controlled, non-randomized, single dose, multiple-course, multicenter study. Further details including subject selection, treatment, and dosage included in protocol.

Progress: Accrual continues in this trial; treatment delays due to prolonged neutropenia have hindered the antineoplastic effects. A total of 16 patients have been accrued at all sites.



# Detail Summary Sheet

Date: 1 Oct 94	Protocol Number: C-93-33	Status: Ongoing
Title: S <sub>2</sub> Triggered MUGA for Assessment of Diastole by LTC Michael D. Lecce, MC		

Start date: Oct 92	Estimated completion date:
Principal Investigator: Michael D. Lecce, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s): Douglas G. Ebersole, M.D. Terry Bauch, M.D. James Heironimus, M.D. Neil Katz, M.D.
Key Words:	
Cumulative MEDCASE cost: 0	Estimated cumulative OMA cost: 0

Number of subjects enrolled during reporting period:	<u>5</u>
Total number of subjects enrolled to date:	<u>13</u>
Periodic review date:	<u>5 Aug 94</u> Review results: _____

Objective(s): To establish the feasibility and potential clinical utility of Multi-Gated Blood Pool imaging using heart sounds as a trigger for image acquisition.

Technical Approach: The initial study will focus on: 1) The ability of this institution to use HSG for MUGA, 2) Compare the results of HSG Blood pool imaging to currently used technology and, 3) Establish institutional norms with the data acquired.

Progress: Several successful studies acquired; new sound transducer in use and accompanying results found. Presentation of results at national meeting anticipated.

# Detail Summary Sheet

Date: 1 Oct 94      Protocol Number: C-93-37      Status: Ongoing

Title: Proposal for Research Model to Investigate Possible Hormone Manipulations in the Treatment of HIV Infections Using Variations in Cell Culture Medium to Test for Facilitators and Inhibitors from the Hormone Family

Start date: 19 Mar 93	Estimated completion date: Spring 94
Principal Investigator: Kevin Carlin, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Endocrinology	Associate Investigator(s): Ron Kennedy Stephanie Anderson Isidoro Chapa John W. Kelly, M.D. Gerald Merrill/Albert Thomason, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): HIV's entrance into a cell and subsequent pirating of the intracellular mechanisms bypasses the usual steps in cellular function. HIV's ability to infect cells and/or take over the functions of the cell, may be facilitated and/or inhibited by various hormone levels. If this was found to be true perhaps a hormone manipulation could be designed to enhance therapy.

Technical Approach: Specifics are given in protocol.

Progress: We are currently examining effect of Triac and Tetrac (thyroid analogues) upon HIV replication in vitro (cell culture and T cells).

# Detail Summary Sheet

Date: 1 Oct 94      Protocol Number: C-93-39      Status: Ongoing

Title: Relationship of Echocardiographic Doppler Indices of Diastolic Function to Severity of Cardiac Transplant Rejection.

Start date: 24 Dec 93	Estimated completion date:
Principal Investigator: Sheri Y. Nottestad, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s): David M. Mego, M.D. Nancy Khan, BSN Bernard J. Rubal, Ph.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 22 patients/42 studies  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: Nov 93      Review results: Nov 93

Objective(s): To determine if serial changes in the echocardiographic Doppler A-Ar interval correlates with grades of cardiac transplant rejection.

Technical Approach: This study is a prospectively designed longitudinal study in which all cardiac transplant patients (n=25) on the transplant service at BAMC will be asked to participate. Following informed consent, 2-D doppler echocardiographic studies will be performed on patients undergoing routine right heart surveillance biopsies.

Progress: Data has been analyzed for all 42 studies performed to date on 22 patients. Early data analysis is encouraging for continuing the study. Presented at ACP meeting already.

# Detail Summary Sheet

Date: 15 Aug 94      Protocol Number: C-93-41      Status: Ongoing

Title: An evaluation of radionuclide angiography and echocardiography for assessment of doxorubicin induced ventricular dysfunction

Start date: 24 Dec 93	Estimated completion date:
Principal Investigator: Douglas G. Ebersole, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s): Terry Jenkins, M.D. Neil Katz, M.D. James Heironimus, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 3  
 Periodic review date:      Review results:     

Objective(s): To determine the effects of doxorubicin on left ventricular diastolic function and to determine if radionuclide angiographic and/or echocardiographic parameters of diastolic dysfunction reliably precede doxorubicin-induced systolic dysfunction reliably precede doxorubicin-induced systolic dysfunction. this could allow the clinician to adjust or discontinue doxorubicin therapy before potentially irreversible loss of systolic function occurs.

Technical Approach: It is proposed that to test the hypothesis that, in patients receiving doxorubicin therapy, radionuclide angiographic and echocardiographic markers of left ventricular diastolic dysfunction reliably precede the loss of left ventricular systolic function. Specifics in protocol.

Progress: Enrollment by Hem/Onc slower than expected.

# Detail Summary Sheet

Date: 7 Nov 94                      Protocol Number: C-93-43                      Status: Ongoing

Title: Effects of the Nicotine Patch on Esophageal Motility

Start date: 24 Jan 93	Estimated completion date:
Principal Investigator: Henri Renom DeLaBaume, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s): Shailesh C. Kadakia, M.D. Richard T. Shaffer, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 10  
 Total number of subjects enrolled to date: 10  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine if the use of the nicotine patch has any effects on esophageal manometry studies.

Technical Approach: A total of 20 volunteers will be enrolled. These will consist of 20 healthy non-smoking adult volunteers. Age and sex will be noted for demographic data. Exclusion criteria will include pregnancy, chronic ETOH use, and any chronic medical conditions requiring medications that cannot be discontinued during the study period. Further details in protocol.

Progress: Investigator did not provide an annual report. Exact status of protocol is unknown.

# Detail Summary Sheet

Date: 25 Aug 94      Protocol Number: C-93-44      Status: Completed

Title: A Phase I Trial of Mitoxantrone Combined with Alpha-Interferon in Patients with Advanced Solid Tumors

Start date: 24 Jan 93	Estimated completion date: Jan 94
Principal Investigator: Howard A. Burris, III, M.D.	Facility: UTHSCSA, CTSC Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Allison M. Thurman, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2 at BAMC

Total number of subjects enrolled to date: 2

Periodic review date: 31 Dec 93      Review results: Continue

Objective(s): To determine the maximally tolerated dose of Mitoxantrone given intravenously every 21 days combined with a fixed subcutaneous dose of Alpha-Interferon in patients with advanced solid tumors. To determine the quantitative and qualitative toxicities of Mitoxantrone and interferon administered in combination. To determine the recommended dose for Mitoxantrone and Interferon on this schedule for Phase II trials. To collect information about the antitumor activity of Mitoxantrone and Interferon on this schedule.

Technical Approach: Drug information, eligibility criteria, treatment plan, dosage modifications and specifics outlined in protocol.

Progress: This trial is closed to accrual with a Maximum tolerated dose (MTD) of 14 mg/m<sup>2</sup> of Mitoxantrone and 5 million units of Alpha Interferon daily x 5 determined. Responses were noted in patients with hepatoma and sarcoma. Consideration for additional phase II trials is being given.

# Detail Summary Sheet

Date: 25 Aug 94 Protocol Number: C-93-45 Status: Ongoing

Title: IND/IDE Trial of the Osteoport: A New Intraosseous Access Device

Start date: 27 Aug 92	Estimated completion date: May 94
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 4  
 Periodic review date: 31 Dec 93 Review results: Continue

Objective(s): To determine the tolerance and clinical suitability of implanting the Osteoport™ in the iliac crest of patients who have failed at least one conventional venous access device. To determine the systemic bioavailability and the absorption rate profile of intraosseously (IO) administered morphine. To initiate an Experience of Use phase to determine longer term tolerance and estimated complication rates.

Technical Approach: Detailed specifics outlined in protocol.

Progress: Accrual to this clinical trial is complete and the results have been submitted to the FDA for a new device approval. Additional patients will be considered to further assess tolerability. A manuscript has been submitted to the New England Journal of Medicine.

# Detail Summary Sheet

Date: 1 Oct 94 Protocol Number: C-93-47 Status: Ongoing

Title: Validation of a Nonlinear Three Element Model for Estimating Stroke Volume and Aortic Flow Wave Form Morphology in Man

Start date: 24 Jan 93	Estimated completion date:
Principal Investigator: Bernard J. Rubal, Ph.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s): Karel H. Wesseling, Ph.D. John M. Karemaker, Ph.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 1  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To test the validity of a three-element nonlinear model for estimating aortic flow waveform morphology in man.

Technical Approach: This study will be a retrospective study in which flow waves derived from a three element non-linear Windkessel model<sup>2</sup> are compared to directly recorded electromagnetic flow/velocity waveforms. Details including data analysis included in protocol.

Progress: Progress on this project has been hampered by bioinstrumentation problems. Study is ongoing.



# Detail Summary Sheet

Date: 21 Oct 94 Protocol Number: C-93-49 Status: Ongoing

Title: Monokine Production in Patients Infected with Mycobacterium Tuberculosis and Human Immunodeficiency Virus

Start date: 23 Dec 92	Estimated completion date:
Principal Investigator: David P. Dooley, M.D.	Facility: SA State Chest Hosp; Brooke Army Medical Center, Texas
Department/Service: Medicine/Infectious Disease	Associate Investigator(s): Greg Anders, M.D. Rebecca A. Cox, Ph.D. Kenneth Kemp, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2  
Total number of subjects enrolled to date: 3 as of 1 Oct 94  
Periodic review date: 21 Oct 94 Review results:

Objective(s): The goal of this investigation is to determine if tuberculosis causes an increased production of the monokines tumor necrosis factor-alpha (TNF-a), interleukin-1B (IL-1), and interleukin-6 (IL-6) in persons infected with the human immunodeficiency virus (HIV). The specific aims will be to compare the in vitro monokine responses of purified blood monocytes, total peripherinuclear cells, and alveolar macrophages from four study groups: patients with concurrent Mycobacterium tuberculosis (MTB) and HIV infection; tuberculosis patients who are HIV-seronegative; patients with HIV infection without evidence of tuberculosis; and healthy, nontuberculous subjects who are seronegative for HIV.

Technical Approach: Description of subjects/controls, experimental design/methods, data collection and statistical analysis included in protocol.

Progress: Message amplification for the housekeeping gene, HPRT, and the cytokines IFN-y and IL-4 has been optimized; preliminary data obtained from PBMC obtained from the different donor groups is shown (appendix 1; sample gel, appendix 2). As can be seen, the production of IFNy was observed when PBMC from all groups were stimulated for 24 h with live BCG (a TB-specific organism). Although data suggests that IFN-y production is not the discriminator between successful or unsuccessful control of MTB disease, this

cytokine may have been released from NK cells on exposure to BCG, and the response may be non-specific. However, a trend may have appeared demonstrating the lack of production of IL-4 (suggesting the absence of a suppressing TH2 response) from PBMC isolated from skin C-93-49 (continued)

test-positive donors, as compared to more variable responses from patients or skin test-negative donors. Cytokine amplifications for other cytokines of interest have been performed and preliminary data is reported (appendices 3 and 4) on results obtained from cells (PBMC and BAL cells) from patients and normal donors. These assays have not yet been optimized to our satisfaction and no conclusions are suggested. BAL cells from one normal donor (the PI) and from two patients and lung samples from a lobectomy performed on a aTCID patient with a tuberculous lung, have been harvested and await message amplification. We are reluctant to perform these assays until the additional cytokine amplifications (IL-2, IL-10, IL-12, TNF-a, and TGF-b) have been perfected so as not to waste these valuable materials.

# Detail Summary Sheet

Date: 25 Aug 94      Protocol Number: C-93-52      Status: Completed

Title: Gemcitabine as Palliative Therapy in Patients with Progressive Carcinoma of the Pancreas

Start date: 7 Dec 92	Estimated completion date: Feb 94
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1

Total number of subjects enrolled to date: 5

Periodic review date: 31 Dec 93      Review results:

Objective(s): To assess the clinical benefit of gemcitabine therapy in patients with progressive cancer of the pancreas as measured by significant improvement in pain, performance status, or weight change. Also, to measure time to progressive disease, survival, objective tumor response rates, duration of clinical benefit response, and univariate assessments of the primary variables. To assess differences in the population pharmacokinetics in these patients.

Technical Approach: Detailed specifics outlined in protocol.

Progress: Accrual is complete on this trial with a total of 70 patients entered nationally, 17 here in San Antonio. Preliminary results look encouraging for the role of Gemcitabine in pancreatic cancer. The data is being analyzed and will be submitted to ASCO in Dec 94.

# Detail Summary Sheet

Date: 25 Aug 94      Protocol Number: C-93-53      Status: Completed

Title: Gemcitabine Versus 5-Fluorouracil in a Randomized Trial as First-Line Palliative Therapy in Patients with Carcinoma of the Pancreas

Start date: 7 Dec 92	Estimated completion date: Jun 94
Principal Investigator: Howard A. Burris, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 4  
 Periodic review date: 31 Dec 93      Review results: Continue

Objective(s): To establish an advantage in clinical-benefit of gemcitabine over 5-fluorouracil (5-FU) in pain, performance status, or weight change. Also, to compare the treatment arms with respect to time to progressive disease, survival, objective tumor response rates, duration of clinical-benefit response, and univariate assessments of the primary variables. To assess differences in the population pharmacokinetics in patients treated with gemcitabine and 5-FU.

Technical Approach: Detailed specifics in protocol.

Progress: Accrual has been completed and the unblinded results will be presented in September 1994. Abstracts are being submitted to the national oncology meetings, and a manuscript will follow shortly.

# Detail Summary Sheet

Date: 25 Aug 94      Protocol Number: C-93-54      Status: Completed

Title: A Phase I Trial of LY231514 Administered as a 30 Minute Infusion Every 7 Days"

Start date: 23 Mar 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2  
 Total number of subjects enrolled to date: 9  
 Periodic review date: 31 Dec 93      Review results: Continue

Objective(s): To determine the maximum tolerated dose of LY231514 administered as a bolus injection given every 7 days. To determine the qualitative and quantitative toxicities of LY231514 on this schedule. To determine the recommended dose of LY231514 on this schedule for Phase II trials. To characterize the pharmacokinetics/pharmacodynamics of LY231514. To collect information about the antitumor effects of LY231514.

Technical Approach: Specifics outlined in protocol.

Progress: This phase I trial is complete and a manuscript is being prepared and edited for submission. Dose limiting toxicities centered around reversible neutropenia, and overall, the treatment was well tolerated. Alternative schedules are being explored in an attempt to achieve greater dose intensity.

# Detail Summary Sheet

Date: 25 Aug 94      Protocol Number: C-93-56      Status: Completed

Title: Phase II Trial of RP56976 in Patients with Advanced Cutaneous Malignant Melanoma

Start date: 23 Mar 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 2  
 Periodic review date: 31 Dec 93      Review results: \_\_\_\_\_

Objective(s): To estimate the major objective response rate and duration of response of RP 56976 in patients with advanced cutaneous malignant melanoma previously untreated with cytotoxic chemotherapy.  
 To determine the qualitative and quantitative toxicity and reversibility of toxicity of RP 56976 administered as an intravenous infusion over one hour every 21 days.  
 To determine the pharmacokinetics of RP 56976 in patients with malignant melanoma.

Technical Approach: Detailed specifics in protocol.

Progress: This trial has completed accrual with a total of 40 patients enrolled in San Antonio and Houston. Five objective responses were observed (12.5%). Discussions regarding further studies with Taxotere in melanoma are being held.

# Detail Summary Sheet

Date: 25 Aug 94      Protocol Number: C-93-57      Status: Completed

Title: A-Phase I Bioavailability Study of Intravenous Versus Oral Hydroxyurea

Start date: 23 Mar 93	Estimated completion date: Jan 94
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 3  
 Periodic review date: 31 Dec 93      Review results: \_\_\_\_\_

Objective(s): To characterize the pharmacokinetic parameters (half-life, clearance, distribution) of orally and intravenously administered hydroxyurea. To determine the systemic availability of oral hydroxyurea.

Technical Approach: Specifics outlined in protocol.

Progress: This pharmacokinetic (PK) study has been completed. Oral hydrea is 100% bioavailable. PK parameters for the two routes of administration were nearly identical. Results were presented at the ASCO meeting in Dallas, May 94.

# Detail Summary Sheet

Date: 7 Nov 94      Protocol Number: C-93-64      Status: Ongoing

Title: Effect of Omeprazole on Blood Alcohol Levels After Oral and Intravenous Ethanol

Start date: 25 Mar 93	Estimated completion date:
Principal Investigator: Carole A. Buckner, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s): Murray Francis, D.O. Shailesh Kadakia, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 5  
 Total number of subjects enrolled to date: 5  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine whether or not omeprazole has an effect on blood alcohol levels after oral and intravenous ethanol in normal, healthy volunteers.

Technical Approach: Twenty-two male subjects between the ages of 21 and 50 who are eligible for medical care at BAMC will be enrolled. They will be non-smokers and will be social drinkers who consume no more than two liters of beer a week or no more than one drink per day. They will not be on Antabuse or Flagyl, and must not have used any H<sub>2</sub>-receptor antagonists in the previous 2 weeks. Study will be conducted in four phases as outlined in protocol.

Progress: Data collection and analysis still in progress.



# Detail Summary Sheet

Date: 15 Aug 94      Protocol Number: C-93-65      Status: Ongoing

Title: Effect of Supportive Interventions on Patient Perception of Musculoskeletal Pain During Cardiac Catheterization

Start date: 25 Mar 93	Estimated completion date:
Principal Investigator: Lois Miller, RN	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s): Sheri Y. Nottestad, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 18  
 Total number of subjects enrolled to date: 18  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To test the effect of back and arm support interventions on the patients' perception of musculoskeletal pain during cardiac catheterization.

Technical Approach: There is a need to develop methods for reducing both the musculoskeletal pain and the consequent use of analgesics and narcotics to accomplish a level of comfort during cardiac catheterization. Details outlined in protocol.

Progress: No further patients enrolled-data results now under statistical analysis by LTC Richards, A.N.. Preliminary results show there is a difference in patient perception of musculoskeletal pain between central and group receiving compact measures.

# Detail Summary Sheet

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Date: 3 Oct 94                      Protocol Number: C-93-66                      Status: Ongoing

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Title: Myocardial Imaging Utilizing Positron Emission Tomography to Detect and Assess Coronary Artery Disease

Start date: 25 Mar 93	Estimated completion date: Unknown
Principal Investigator: Douglas G. Ebersole, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s): Landon Wellford, M.D. Neil Katz, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): Evaluation of the accuracy and utility of Positron Emission Tomography in the detection and assessment of coronary artery disease.

Technical Approach: Detailed specifics given in protocol.

Progress: Personnel at the PET Center has recently changed and we are now actively seeking subjects to enroll.

# Detail Summary Sheet

Date: 25 Aug 94      Protocol Number: C-93-67      Status: Terminated

Title: Evaluation of Diaphragmatic Function in Patients Receiving a Prolonged Course of High-Dose Prednisone for Interstitial Lung Disease

Start date: 25 Mar 93	Estimated completion date:
Principal Investigator: Daniel I. Loube, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Pulmonary Dis/Critical Care	Associate Investigator(s): James E. Johnson, M.D. H. M. Blanton, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_ 1  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine if high dose glucocorticoids lead to worsening diaphragmatic function in humans.

Technical Approach: Patient Selection, experimental design and procedures outlined in protocol.

Progress: Study terminated secondary to lack of satisfactory patients.

# Detail Summary Sheet

Date: 25 Aug 94      Protocol Number: C-93-69      Status: Ongoing

Title: Phase I Study of FCE 24517 in Adults with Advanced or Refractory Solid Tumors

Start date: 9 Apr 93	Estimated completion date: Feb 94
Principal Investigator: Howard A. Burris, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 6  
 Periodic review date: 31 Dec 93      Review results: Continue

Objective(s): To establish the maximally tolerated dose of FCE 24517 when given in divided doses intravenous daily x 3 every four weeks to adult patients with advanced and/or refractory solid tumors. To evaluate the acute toxicities and close limiting toxicity (DLT) of FCE 24517 in this patient population. To document any possible antitumor activity. Although a sufficiently sensitive, bioanalytical procedure for drug quantitation is not available at present, an attempt will be made to collect biofluid samples in order to explore possible concentration-response relationship.

Technical Approach: This is a dose finding study in patients with advanced and/or refractory tumors. The study will be open label and non-randomized. Based on preclinical toxicity data and Phase I Experience to date in europe, the initial starting dose of FCE 24517 will be 100 mcg/M<sub>2</sub> administered in three equally divided daily doses. The maximum tolerated dose level, based on single intravenous bolus injection, has not yet been determined based on European Phase I studies at doses up to and including 750 mcg/M<sup>2</sup>. Details included in protocol.

Progress: Accrual to this trial has been rapid and only 2 patients remain to be entered. The Dose Limiting Toxicity (DLT) myelosuppression. No objective tumor responses have been observed to date. Broad phase II testing is planned with this agent.

# Detail Summary Sheet

Date: 3 Oct 94 Protocol Number: C-93-70 Status: Completed

Title: Active Immunization of AZT-Treated HIV Infected Patients with Recombinant GP160 HIV Protein: Phase I/II Study of Immunogenicity, Toxicity, and Effect in "in vivo" Immunoregulation

Start date: 17 Nov 92	Estimated completion date:
Principal Investigator: J. William Kelly, M.D.	Facility: DAH, and BAMC
Department/Service: Medicine/Infectious Disease	Associate Investigator(s): C. Kenneth McAllister, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 16  
 Total number of subjects enrolled to date: 25  
 Periodic review date: Review results:

Objective(s): To conduct a Phase 1/2 trial of the recombinant human immunodeficiency virus (HIV) envelope glycoprotein, gp160 candidate vaccine, in patients with HIV infection while on AZT. Specific objectives include: 1) to continue to evaluate the immunogenicity and toxicity of this product; 2) to determine the parameters predictive of immunoresponsiveness; and 3) to determine the clinical efficacy of immunization with gp160 in the treatment of HIV infection.

Technical Approach: As outlined in the study protocol.

Progress: 16 patients were treated. All completed one year course of therapy. Results are being analyzed.

# Detail Summary Sheet

Date: 3 Oct 94      Protocol Number: C-93-71      Status: Ongoing

Title: A Double-Blind, Placebo Controlled, Parallel Group, Multicenter Study of the Use Of Weekly Azithromycin as Prophylaxis Against the Development of Mycobacterium avium Complex Disease in HIV Infected People

Start date: 1 Apr 93	Estimated completion date:
Principal Investigator: J. William Kelly, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Infectious Disease	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 1  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To evaluate the safety and efficacy of azithromycin administered once a week in the prevention of disseminated MAC in severely immunocompromized HIV infected patients with a CD4 count <100/ $\mu$ l.

Technical Approach: Selection of subjects, inclusion/exclusion criteria, study design, drug administration, etc. are outlined in protocol.

Progress: One patient continued on followup. No new patient sentered on study.

# Detail Summary Sheet

Date: 25 Aug 94      Protocol Number: C-93-73      Status: Ongoing

Title: A Phase II Study of Flutamide in Patients with Pancreatic Adenocarcinoma

Start date: 1 May 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 1  
 Periodic review date: 31 Dec 93      Review results: Continue

Objective(s): To evaluate the clinical benefit of flutamide in patients with advanced pancreatic adenocarcinoma as evidenced by improvement in pain control, performance status, or nutritional status.

Technical Approach: Eligibility criteria, descriptive factors, response criteria, etc., covered in protocol.

Progress: Accrual continues on this study. Evidence for clinical benefit has been observed. A total of 14 patients will be enrolled at which time the data will be analyzed regarding further accrual.

# Detail Summary Sheet

Date: 1 Oct 94      Protocol Number: C-93-74      Status: Ongoing

Title: A Phase I Dose Finding Clinical Trial to Evaluate the Safety and Pharmacokinetics of DMP 840 Given Daily for Five Consecutive Days (DX5) Every Four weeks in Cancer Patients with Refractory Solid Tumors

Start date: 6 May 93	Estimated completion date: 1 Jun 94
Principal Investigator: Patrick Cobb, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words: DMP 840 Cancer Pharmacokinetics	
Cumulative MEDCASE cost: None	Estimated cumulative OMA cost: None

Number of subjects enrolled during reporting period: 2  
 Total number of subjects enrolled to date: 9  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine the maximum tolerated dose (MTD) and the recommended dose (RD) for subsequent Phase II trials of DMP 840. To determine dose limiting toxicities (DLTLs) of DMP 840, including qualitative and quantitative toxicities, and to define their duration and reversibility. To evaluate the pharmacokinetics of intravenous DMP 840 administered on single daily doses for five consecutive days, as related to toxicity. To document any antitumor activity observed.

Technical Approach: Inclusion/exclusion criteria, study procedures, safety parameters, study medications and other specifics outlined in protocol.

Progress: Utilizing a brief-infusion schedule, a maximally tolerated dose of 14.0 mg/m<sup>2</sup> was found in minimally pre-treated patients. The dose-limiting toxicity was myelosuppression. Given the short initial half-life of the drug, patients are now being enrolled on a 120-hr infusion schedule. One patient at 10 mg<sup>2</sup>/day experienced grade 4 thrombocytopenia, other patients are being enrolled to further define toxicity. No complete or partial remissions have been seen to date.



# Detail Summary Sheet

Date: 25 Aug 94      Protocol Number: C-93-75      Status: Ongoing

Title: Phase I Evaluation of API-395 Administered Intravenously Every 14 Days

Start date: 6 May 93	Estimated completion date:
Principal Investigator: Howard A. Burris, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 31 Dec 93      Review results: Continue

Objective(s): To determine maximum tolerated dose (MTD) of API-395 and to assess cumulative toxicity of repetitive cycles of treatment every 14 days; to collect information about antitumor effects of API-395; and characterize the toxicities associated with API-395 treatment.

Technical Approach: Study population, treatment plan, toxicities to be monitored, dosage modifications and specifics outlined in protocol.

Progress: The opening of this study has been delayed because of the sale of API-395 (Oxaloplatin) from Axion to a French pharmaceutical firm. We anticipate this trial opening in late 1994, and will notify you accordingly prior to commencement.

# Detail Summary Sheet

Date: 1 Oct 94      Protocol Number: C-93-77      Status: Ongoing

Title: High-Dose Chemotherapy and Total Body Irradiation with Autologous Stem Cell Support and Alpha Interferon Consolidation in the Treatment of Patients with Non-Hodgkin's Lymphoma with a Poor Prognosis

Start date: 13 May 93	Estimated completion date:
Principal Investigator: W. Jeffrey Baker, M.D.	Facility: UTHSCSA & Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 1  
 Periodic review date: May 94      Review results: \_\_\_\_\_

Objective(s): To assess the efficacy of fractionated total body irradiation, VP-16, and cyclophosphamide with autologous hematopoietic stem cell transplantation in the treatment of selected patients with poor-prognosis, low-grade lymphoma.

To assess the effect of post-transplant consolidation therapy with alpha interferon in patients who have achieved a complete response to high-dose chemoradiotherapy and ASCT.

To assess the prognostic value of serial monitoring of bcl-2 and bcl-1 gene rearrangements as markers of residual lymphoma cells.

Technical Approach: Eligibility criteria, treatment plan, drug information and specifics outlined in protocol.

Progress: We have treated one patient on this protocol and he had prolonged neutropenia and died from fungemia at day 45. The University also has tested 3 patients on this protocol and all 3 patients have prolonged neutropenia with very severe mucositis due to VP<sub>16</sub>. We are planning to D/C VP16. Furthermore, we are unable to answer the question L-Inf. In addition patients >75 years old will get chemotherapy only. Because of several major changes, this protocol will be closed and replaced with "High-Dose Chemotherapy with or without Total Body Irradiation with Autologous Stem Cell Support and Alpha Interferon Consolidation in the Treatment of Patients with Non-Hodgkin's Lymphoma with a Poor Prognosis.



# Detail Summary Sheet

Date: 15 Aug 94      Protocol Number: C-93-79      Status: Ongoing

Title: The Effect of Bronchoalveolar Lavage Volume on the Diagnosis of Peripheral Primary Lung Cancer

Start date: 26 May 93	Estimated completion date: 1995
Principal Investigator: John F. Theroux, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Pulmonary Disease	Associate Investigator(s): James E. Johnson, M.D. W. Kenneth Linville, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 10  
 Total number of subjects enrolled to date: 20  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine whether the use of a larger volume of brnchoalveolar lavage fluid increases the diagnostic yield of BAL cytology in peripheral, primary lung cancers.

Technical Approach: Patients undergoing FOB for evaluation of solitary lung masses will be asked to enroll. Of those that enroll, subjects will be included if they have no visible endobronchial disease during bronchoscopy and an ultimate diagnosis of cancer is made. Methods, data collection, statistical analysis, etc. included in protocol.

Progress: Twenty patients enrolled, however, 2 excluded due to benign diagnoses and one due to visible endobronchial disease. Recruitment of patients continues. To date, the volume of BAL used has not affected the efficacy of this diagnostic procedure.

# Detail Summary Sheet

Date: 4 Oct 94 Protocol Number: C-93-80 Status: Completed

Title: The Effect of Omeprazole on Iron Absorption in Healthy Volunteers

Start date: 14 May 93	Estimated completion date:
Principal Investigator: John G. Carrougner, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s): David A. Rinaldi, M.D.
Key Words:	Shaleish Kadakia, M.D.
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 10  
 Total number of subjects enrolled to date: 10  
 Periodic review date: Review results:

Objective(s): To determine if the oral absorption of ferrous sulfate using the iron tolerance test is reduced in healthy volunteers during a state of reduced gastric acidity, as induced by the gastric proton pump inhibitor, omeprazole. To determine whether the absorption of ferrous sulfate can be improved using ascorbic acid during a state of reduced gastric acidity, as induced by omeprazole.

Technical Approach: Eleven healthy volunteers will be enrolled in the study. Specifics including inclusion/exclusion criteria, study outline, etc., outlined in protocol.

Progress: This study has been completed with 25 patients enrolled. Data is being compiled by Dr. Thomas Kepczyk who has PCS'd to Fitzsimons AMC. Study completed.

# Detail Summary Sheet

Date: 15 Aug 94      Protocol Number: C-93-81      Status: Ongoing

Title: Occurrence of Obstructive Sleep Apnea in Pregnant Women and an Evaluation of Its Impact on Fetal Outcome

Start date: 13 May 93	Estimated completion date: Jul 94
Principal Investigator: Daniel I. Loube, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Pulmonary Disease/Crit Care	Associate Investigator(s): Manuel L. Morales, M.D. Mark D. Peacock, M.D. Herman M. Blanton, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 300  
 Total number of subjects enrolled to date: 300  
 Periodic review date: Review results:

Objective(s): To determine the incidence of obstructive sleep apnea (OSA) in pregnant women; and to evaluate the possible impact on OSA in pregnant women on fetal development and outcome.

Technical Approach: Statement of hypotheses, overview, experimental design, statistical analysis, etc, outlined in protocol.

Progress: Study indicates pregnant women snore significantly more than non-pregnant age matched women. This indicates increased upper airway resistance, which is epidemiologically related to OSA. However, we have only found two pregnant women with OSA, similar to what is expected in the normal population, but higher than previously reported for pregnancy (trend only). There have been no changes since the last report submission.

# Detail Summary Sheet

Date: 1 Oct 94      Protocol Number: C-93-83      Status: Ongoing

Title: High-Dose Taxol, Cyclophosphamide, and Cisplatin (Taxol/CPA/cDDP) with Autologous Bone Marrow Support (ABMS) for Metastatic Breast Cancer

Start date: 10 Jun 93	Estimated completion date:
Principal Investigator: Svetislava J. Vukelja, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 11  
 Total number of subjects enrolled to date: 11  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine the toxicity, time to marrow reconstitution, response rate and time to treatment failure of high-dose combination chemotherapy with taxol, cyclophosphamide and cisplatin, followed by autologous marrow infusion in eligible patients with metastatic breast cancer. To provide a new drug in combination with other chemotherapeutic agents in management of individual patients with advanced breast cancer.

Technical Approach: Patient eligibility, descriptive factors, treatment plan, etc, outlined in protocol.

Progress: We have entered 11 patients to date (Walter Reed has entered 9 to total of 20 patients. Here are the results. At BAMC, we had one death at day 8 after high dose due to fungemia; one patient relapsed at 2 months (she had lots of disease going on; one patient relapsed at 11 months. All other patients at BAMC are disease free at 14 months, F/U (mean 5 months). One patient had inversion of disease-free interval (her 1st remission was 10 months but her remission after high-dose chemotherapy is 14 months. Walter Reed had 3 additional patients that have relapsed. This still gives us 64% response rate with 29% complete remission and 35% partial remission. I am presenting this data at a Bone Marrow Transplant Meeting in August 1994.

# Detail Summary Sheet

Date: 15 Aug 94      Protocol Number: C-93-84      Status: Terminated

Title: A Randomized Trial of Filgrastim at a Fixed Dose in Patients Undergoing Intensive Chemotherapy

Start date: 1 Jun 93	Estimated completion date:
Principal Investigator: Scott C. Martin, RPH	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Timothy J. O'Rourke, M.D. Svetislava J. Vukelja, M.D. Ralph F. Heaven, M.D.
Key Words:	
Cumulative MEDCASE cost: 0	Estimated cumulative OMA cost: 0

Number of subjects enrolled during reporting period: 5  
 Total number of subjects enrolled to date: 5  
 Periodic review date: - Review results: -

Objective(s): Does G-CSF therapy starting 3 days post chemotherapy at a fixed 300 mcg dose prevent neutropenic febrile admissions in patients undergoing intensive chemotherapy treatment?

Technical Approach: Patient eligibility, study methodology, study medications, statistical analysis, etc, outlined in protocol.

Progress: Twenty-seven patients were enrolled. No patient receiving G-CSF was admitted for neutropenia fever. Three patients not receiving G-CSF were admitted for a neutropenic fever. Inability to accrue enough patients in a timely fashion, partly due to previously interested medical centers deciding not to participate, dictates terminating the protocol. No adverse reaction seen.



# Detail Summary Sheet

Date: 25 Aug 94      Protocol Number: C-93-87      Status: Completed

Title: Phase I Study of Topotecan Administered on a Daily Times Five Schedule with a Single Infusion of Cisplatin Every Three Weeks to Patients with Advanced Non-Small Cell Lung Carcinoma

Start date: May 93	Estimated completion date: Mar 94
Principal Investigator: Howard A. Burris, III, M.D.	Facility: UTHSCSA & Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 4  
 Periodic review date: 31 Dec 93      Review results:

Objective(s): To determine the maximally tolerated dose (MTD) of topotecan administered on a daily times five schedule every 3 weeks with a single infusion of cisplatin.

To determine the quantitative and qualitative toxicities of topotecan administered on a daily times five schedule with cisplatin. Also to assess antitumor activity of topotecan in combination with cisplatin, including objective responses in patients with measurable disease.

Technical Approach: Study design, population, treatment, and detailed specifics outlined in protocol.

Progress: A total of 10 patients were enrolled on this trial with a Maximum Tolerated Dose (MTD) of Topotecan 1.0 mg/m<sup>2</sup> and Cisplatin 75 mg/m<sup>2</sup> determined. Three objective responses were noted. Phase II trials of this combination are being planned. Results were presented at the EORTC meeting in Amsterdam, Mar 94.

# Detail Summary Sheet

Date: 25 Aug 94      Protocol Number: C-93-88      Status: Ongoing

Title: A Phase III Open-Label, Multicenter Trial of Actimmune Interferon Gamma-1b (rIFN-γ 1b) in Patients with Metastatic Renal Cell Carcinoma

Start date: 16 Jun 93	Estimated completion date: Apr 94
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 1  
 Periodic review date: 31 Dec 93      Review results: Continue

Objective(s): To determine the durable complete response rate (defined as a complete response of greater than 6 months' duration) of 100 μg of Actimmune administered subcutaneously once every 7 days to patients with metastatic renal cell carcinoma.

Technical Approach: Detailed specifics given in protocol.

Progress: Accrual is being completed nationally. A total of 14 patients have been enrolled in San Antonio with 2 objective responses noted. No toxicity problems to date.

# Detail Summary Sheet

Date: 25 Aug 94      Protocol Number: C-93-89      Status: Ongoing

Title: A Phase II Study to Determine the Anti-Tumor Effect of Intravenous Ilmofofosine Administered as a 120-Hour Infusion Every 21 Days to Patients with Ovarian Cancer

Start date: 16 Jun 93	Estimated completion date: Aug 94
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 31 Dec 93      Review results: Continue

Objective(s): To assess the antitumor effect of five day (120-hr) infusion of intravenous ilmofofosine in patients with ovarian cancer; to assess the toxicity of ilmofofosine; to evaluate the serum concentration-time profile of ilmofofosine and the sulfoxide metabolite at steady state.

Technical Approach: Accrual continues. Therapy has been well tolerated to date. An interim analysis will be performed on 20 patients.

Progress: Accrual continues. Therapy has been well tolerated to date. An interim analysis will be performed on 20 patients.

# Detail Summary Sheet

Date: 1 Oct 94 Protocol Number: C-93-91 Status: Ongoing

Title: A Randomized, Double Blind, Placebo-Controlled Study of Parallel Design to Evaluate and Compare the Therapeutic Implant 5FU-e TI (5003) to its Placebo Vehicle when Administered to Patients with External Condylomata Acuminata

Start date: 30 Jun 93	Estimated completion date: 30 Jun 94
Principal Investigator: Dirk M. Elston, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Dermatology	Associate Investigator(s): Jeffrey Stiles, M.D. Norvell Coots, M.D. Richard Vinson, M.D. Donna Corvette, M.D. Mark Peake, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 3  
Periodic review date: Annually/June Review results:

Objective(s): To evaluate the safety and efficacy of the Therapeutic Implant (5-FU-eTI 5003) with and without epinephrine, when administered in six weekly injections to male and female patients with external condylomata as compared to placebo gel (collagen). To describe the response rate, the time to recurrence and cumulative recurrence rate of condylomata in patients treated as outlined above. To evaluate the safety and efficacy of treatment in collagen skin test positive patients. Pharmacokinetics: To determine fluorouracil levels in plasma after initial injection in patients with a total wart area > 199mm<sup>2</sup> (optional).

Technical Approach: Study design, inclusion/exclusion criteria, treatment plan and detailed specifics given in protocol.

Progress: Three patients completed the treatment phase of the study. One patient remains in the follow-up phase, free of all warts. The second patient withdrew from the follow-up phase in order to seek treatment for non-target warts. (Non-target warts appeared during the treatment phase and were not eligible for treatment with the study drug). The non-target warts responded to other therapy, and the patient remains free of all warts. The third patient withdrew from the follow-up phase in order to seek treatment for non-target warts. Some non-target warts, as well as recurrences of target warts,

C-93-91 continued

persist. The patient is still undergoing treatment at BAMC.

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# Detail Summary Sheet

Date: 25 Aug 94      Protocol Number: C-93-92      Status: Ongoing

Title: A Phase I Trial of DS-4152 Administered as an Infusion Every 21 Days

Start date: 28 Jun 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2  
 Total number of subjects enrolled to date: 2  
 Periodic review date: 31 Dec 93      Review results: Continue

Objective(s): To determine the maximum tolerated dose of DS-4152 administered as an infusion every 21 days. To determine the qualitative and quantitative toxicities of DS-4152 on this schedule. To determine the appropriate dose of DS-4152 on this schedule for Phase II trials. To characterize the pharmacokinetics/pharmacodynamics of DS-4152.

Technical Approach: Patient eligibility, treatment plan, pharmacokinetics, toxicity, and specifics given in protocol.

Progress: This trial is nearing completion with a Maximum Tolerated Dose (MTD) of 500 mg/m<sup>2</sup> determined. Additional patients are being accrued at an intermediate dose of 445 mg/m<sup>2</sup> to further assess tolerability. Preliminary results were presented at the European Organization for the Research and Treatment of Cancer (EORTC) meeting in Amsterdam, March 1994.

# Detail Summary Sheet

Date: 25 Aug 94      Protocol Number: C-93-96      Status: Completed

Title: An Open Phase II Trial of ICI D1694 in Subjects with Non-Small Cell Lung Cancer

Start date: 23 Jun 93	Estimated completion date: May 94
Principal Investigator: Howard A. Burris, III, M.D.	Facility: UTHSCSA; St. Luke's & Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 14  
 Periodic review date: 31 Dec 93      Review results: Continue

Objective(s): To estimate the objective response rate (complete or partial response) of ICI D1694 in subjects with advanced non-small cell lung cancer. To characterize further the toxicity profile of ICI D1694.

Technical Approach: Subject selection including inclusion/exclusion criteria and other specifics given in protocol.

Progress: Accrual to this trial is complete with a total of 40 patients enrolled. Two objective responses were observed (5%). The therapy was well tolerated. The drug was felt to have minimal activity in this disease.

# Detail Summary Sheet

Date: 25 Aug 94      Protocol Number: C-93-98      Status: Completed

Title: A Phase II Study of Intravenous Navelbine in Patients with Hormone Refractory Prostate Cancer to Determine Clinical Benefit

Start date: 23 Jun 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility:                    UTHSCSA Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 8  
Periodic review date: 31 Dec 93      Review results: \_\_\_\_\_

Objective(s): To assess the clinical benefit of intravenous Navelbine in patients with hormone refractory prostate cancer (HRPC) as measured by time to disease progression, Karnofsky performance status, and pain palliation. To determine the objective response rate of intravenous Navelbine in those patients with HRPC and measurable disease. To evaluate the qualitative and quantitative toxicities of intravenous Navelbine in patients with HRPC.

Technical Approach: Patient eligibility, treatment plan, drug administration and specifics given in protocol.

Progress: Accrual to this trial is complete. A total of 20 patients were treated and 40% experienced clinical benefit. This therapy was well tolerated. Results were presented at the American Society of Clinical Oncology (ASCO) meeting in Dallas, Texas May 1994. Additional trials are being planned with this agent in prostate cancer.



# Detail Summary Sheet

Date: 25 Aug 94      Protocol Number: C-93-99      Status: Completed

Title: A Phase I Pharmacokinetic Study of Five Daily Intravenous and Oral Doses of Fludarabine Phosphate in Subjects with Advanced Cancer

Start date: 23 Jun 93	Estimated completion date:
Principal Investigator: Timothy O'Rourke, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Karen J. Bowen, M.D. Patrick W. Cobb, M.D. John R. Eckardt, M.D. Gail Eckhardt, M.D. Terry Jenkins, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 9 (3 at BAMC)

Total number of subjects enrolled to date: 9 (3 at BAMC)

Periodic review date:      Review results:     

Objective(s): To characterize the pharmacokinetics of F-ara-A following 5 consecutive daily doses of fludarabine phosphate solution administered orally and intravenously.

To characterize the relative incidence severity and duration of clinical and laboratory adverse events observed in these subjects during study. To compare plasma and urine metabolites after intravenous and oral administration of fludarabine phosphate solution.

Technical Approach: Rationale, study design, inclusion/exclusion criteria, and detailed specifics outlined in protocol.

Progress: Study is completed and manuscript is in process. Patients only received two cycles of treatment on study and thus, all patients are off study. No patients continue on Fludarabine off-study at this time.

# Detail Summary Sheet

Date: 25 Aug 94      Protocol Number: C-93-100      Status: Ongoing

Title: A Pilot Study of the Safety and Efficacy of an Intralesionally Administered Cisplatin Therapeutic Implant (MP 5010) in Patients with Superficially Accessible Tumors of Any History

Start date: 23 Jun 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2  
 Total number of subjects enrolled to date: 6  
 Periodic review date: 31 Dec 93      Review results: Continue

Objective(s): To evaluate the safety and efficacy of the intratumorally administered CDDP TI (MP 5010) in patients with superficially accessible tumors of any history. To observe the tumor responses, and investigate the potential for efficacy and local disease control. To observe the duration of responses, and where biopsy is feasible and accepted by the patient, to observe the effects of intralesional MP 5010 on the histopathology of injected lesions that respond.

Technical Approach: Study design, patient selection criteria, treatment plan, doses, toxicity, etc, outlined in protocol.

Progress: This agent has been well tolerated with good clinical efficacy observed. Results were presented at the ASCO meeting in Dallas, May 94. A manuscript is underway. Several additional patients will be enrolled to assess tolerability.

# Detail Summary Sheet

Date: 15 Aug 94 Protocol Number: C-93-102 Status: Ongoing

Title: The Risk of Hemorrhage in Patients with Interstitial Lung Disease Undergoing Transbronchial Lung Biopsy

Start date: 1 Jul 93	Estimated completion date:
Principal Investigator: Michael J. Morris, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Pulmonary Disease & Crit Care	Associate Investigator(s): Mark D. Peacock, M.D. David Mego, M.D.
Key Words: Hemorrhage, interstitial lung disease, transbronchial biopsy	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 12

Total number of subjects enrolled to date: 25

Periodic review date: Review results:

Objective(s): In a prospective manner this project will determine the incidence of clinically occult pulmonary hypertension (PH) in patients with interstitial lung disease (ILD). Subsequently, the rates of hemorrhage following transbronchial lung biopsy (TBBx) in patients with interstitial lung disease will be compared with regards to the presence or absence of clinically occult PH. We propose that PH detectable only by echocardiography does not increase the risk of hemorrhage during TBBx.

Technical Approach: The hypothesis to be tested is that PH, that is not clinically evident by physical exam and radiographic evaluation, but detectable by echocardiography does not cause increased hemorrhagic complications from transbronchial biopsies. Further specifics in protocol.

Progress: 25 patients have been enrolled into study. There have been no bleeding complications (all patients have had minimal bleeding), although several patients have had mild increase in pulmonary systolic pressures.

# Detail Summary Sheet

Date: 25 Aug 94      Protocol Number: C-93-104      Status: Ongoing

Title: Phase I Trial of VP16 + AMGEN rG-CSF in Patients with Advanced Malignancies

Start date: 30 Jul 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Timothy O'Rourke, M.D. David A. Rinaldi, M.D. Patrick Cobb, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 31 Dec 93      Review results: Continue

Objective(s): To determine the maximally tolerated dose and toxicities of VP16 when combined with r-G-CSF in patients with advanced malignancies.  
 To determine which schedule of administration of r-G-CSF and VP16 is superior in ameliorating toxicity while maximizing potential synergy of the two agents.  
 To determine the recommended dose and schedule of VP16 + r-G-CSF to be used in phase II trials.  
 To document any responses that may occur with this combination.

Technical Approach: Design/methods, subject population, recruitment and other specifics outlined in protocol.

Progress: This protocol has not commenced accrual as an IND# was pending. The # has now been issued by the FDA and arrangements are being made with the sponsor to open the study. We will notify you prior to enrolling patients.

# Detail Summary Sheet

Date: 25 Aug 94      Protocol Number: C-93-105      Status: Completed

Title: Phase I Trial of CT-1510R in Patients with Advanced Refractory Cancer Undergoing Therapy with High-Dose Thiotepa

Start date: 29 Jul 93	Estimated completion date:
Principal Investigator: Howard Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 4  
 Periodic review date: 31 Dec 93      Review results: Continue

Objective(s): To determine the maximum tolerated concentration (MTC) of orally administered CT-1501R in patients with advanced refractory cancer. To determine the pharmacokinetic (PK) profile of CT-1501R including the elimination plasma half-life ( $T_{1/2}$ ), area under the curve (AUC), and plasma clearance ( $C_l$ ) following the first and last dose of CT-1501R during the MTC/PK period.  
 To determine the pharmacokinetic profile of CT-1501R during treatment with thiotepa and the effect of CT-1501R on thiotepa pharmacokinetics.

Technical Approach: Study design, patient selection, treatment definition, adverse experience, data analysis and other specifics outlined in protocol.

Progress: This protocol is closed to accrual and the objectives of the trial have been met. A Maximum Tolerated Dose (MTD) of 80.5 mg/kg was achieved with a dose limiting toxicity (DLT) of nausea and vomiting. Results were presented at the International Growth Factor meeting in Atlanta, Jun 94. A manuscript is being prepared.

# Detail Summary Sheet

Date: 15 Aug 94      Protocol Number: C-93-115      Status: Ongoing

Title: Obstructive Sleep Apnea and Silent Myocardial Ischemia in Post-Myocardial-Infarction Patients: frequency, temporal relationship, and response to nasal continuous positive airway pressure (nCPAP) therapy

Start date: Aug 93	Estimated completion date: Aug 94
Principal Investigator: Terry D. Bauch, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology/Pulm Disease	Associate Investigator(s): Daniel I. Loubé, M.D. Mark D. Peacock, M.D. James K. Gilman, M.D.
Key Words:	
Cumulative MEDCASE cost: 0	Estimated cumulative OMA cost: 0

Number of subjects enrolled during reporting period: 3  
 Total number of subjects enrolled to date: 4  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) Identify obstructive sleep apnea (OSA) in post-myocardial infarction(MI) patients with known risk factors for OSA. 2) Investigate the frequency of, and temporal relationship between episodes of OSA and Silent Myocardial Ischemia (SMI) in post-MI patients. 3) Determine the effect of nCPAP treatment of OSA upon SMI in post-MI patients.

Technical Approach: Subjects, methods, data collection, statistical analysis, etc., outlined in protocol.

Progress: Three patients enrolled. Ten potential subjects identified, enrollment in progress.

# Detail Summary Sheet

Date: 25 Aug 94 Protocol Number: C-93-117 Status: Ongoing

Title: A Phase II Study of Gemcitabine in Patients with Hormone Refractory Prostate Cancer to Determine Clinical Benefit

Start date: Aug 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2  
Total number of subjects enrolled to date: 2  
Periodic review date: 31 Dec 93 Review results: Continue

Objective(s): To assess the clinical-benefit of intravenous gemcitabine in patients with hormone-refractory prostate cancer (HPRC) as measured by Karnofsky Performance Status (KPS), and pain palliation.

Technical Approach: Investigational plan, study population, dosage & administration, concomitant therapy and other specifics covered in protocol.

Progress: It is too early to assess clinical benefits of this study.

# Detail Summary Sheet

Date: 25 Aug 94      Protocol Number: C-93-118      Status: Completed

Title: A Double-Blind Randomized Parallel Study of the Antiemetic Effectiveness of IV Dolasetron Mesylate vs. IV Zofran in Patients Receiving Cisplatin Chemotherapy

Start date: 5 Aug 93	Estimated completion date:
Principal Investigator: Howard A. Burris, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 3  
 Total number of subjects enrolled to date: 9  
 Periodic review date: 31 Dec 93      Review results: \_\_\_\_\_

Objective(s): To compare the effectiveness of a 2.4 mg/kg single intravenous (IV) dose of dolasetron mesylate to a 32 mg single intravenous (IV) dose of ondansetron (Zofran<sup>®</sup>--Glaxo) for complete prevention of emesis due to > 70 mg/m<sup>2</sup> of cisplatin chemotherapy. Secondary objectives will be to compare the effectiveness of a 1.8 mg/kg single intravenous (IV) dose of dolasetron mesylate to a 32 mg single intravenous (IV) dose of ondansetron (Zofran<sup>®</sup>--Glaxo) and to the 2.4 mg/kg single IV dose of dolasetron mesylate for complete prevention of emesis due to > 70 mg/m<sup>2</sup> of cisplatin chemotherapy.

Technical Approach: Study design, materials/methods and specifics outlined in protocol.

Progress: Protocol is closed to accrual and preliminary results reveal greater efficacy with Dolasetron. a total of 300 patients were randomized nationally. A manuscript is being prepared by the leading institutions for the study.



# Detail Summary Sheet

Date: 4 Aug 94      Protocol Number: C-93-119      Status: Terminated

Title: Prospective Single-Blinded Cross-Over Comparison of Fosinopril and Nifedipine in Hypertensive Patients

Start date: Oct 93	Estimated completion date:
Principal Investigator: Edward C. Michaud, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Internal Medicine	Associate Investigator(s): J. Grant Barr, M.D. Steven F. Gouge, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine whether there are differences in efficacy, duration of action, or side effects profiles, of two commonly used antihypertensive agents nifedipine and fosinopril. The hypothesis is that there are no clinically significant differences in the two products and that their duration of action is similar.

Technical Approach: The study will gather data by the use of 24 hour blood pressure monitors, blood sampling for basic electrolytes, Blood Urea Nitrogen, Creatine, Liver Function Tests, and patient questionnaires to be filled out by physician at interview. Details are outlined in protocol.

Progress: All physicians participating in this protocol have PCSd. No one in the Nephrology Service is familiar with this study. Terminate the study.

# Detail Summary Sheet

Date: 15 Aug 94      Protocol Number: C-93-122      Status: Ongoing

Title: A Single Blinded Study Comparing Nightly Versus Every Other Night Versus Weekly Application of Retin-A 0.05% Cream for the Treatment of Comedonal Acne Vulgaris

Start date: Oct 93	Estimated completion date: Jul 95
Principal Investigator: Leo A. Conger, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Dermatology	Associate Investigator(s): Dirk M.Elston, M.D. Mark Peake, M.D. Rick Keller, M.D. Leo Conger, M.D.
Key Words: Acne Retin-A	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 28  
Total number of subjects enrolled to date: 29  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To compare the cost, efficacy and side effect profiles of nightly application versus every other night application versus weekly application of Retin-A cream for the treatment of comedonal (blackheads and whiteheads) acne vulgaris.

## Technical Approach:

Progress: Patient recruitment has been extremely slow. Since Dr. Biediger was transferred to Ft Hood, I have become the principal investigator here at BAMC. Plan is to have patient recruitment from both Ft Sam and Ft Hood.

# Detail Summary Sheet

Date: 1 Oct 94	Protocol Number: C-93-124	Status: Ongoing
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Title: The Effect of Oral D-Sotalol on Mortality in Patients with Atherosclerotic Heart Disease and LV Dysfunction

Start date: 14 Sep 93	Estimated completion date:
Principal Investigator: James K. Gilman, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost: N/A	Estimated cumulative OMA cost: N/A

Number of subjects enrolled during reporting period:	3
Total number of subjects enrolled to date:	3
Periodic review date: N/A	Review results: N/A

Objective(s): To determine whether d-sotalol on Mortality in Patients with Atherosclerotic Heart Disease and LV Dysfunction (resting LV ejection fraction < 40%) and CHD.

To compare the safety and tolerance of d-sotalol with placebo when administered long-term to patients with LV dysfunction (resting LV ejection fraction < 40%) and CHD.

Technical Approach: Study design/eligibility, safety and specifics outlined in protocol.

Progress: Three patients enrolled. No adverse events. Study proceeding well.

# Detail Summary Sheet

Date: 1 Oct 94                      Protocol Number: C-93-125                      Status: Ongoing

Title: Endosonics PTCA Balloon Catheter: Eagle

Start date: 14 Sep 93	Estimated completion date:
Principal Investigator: William T. Wright, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s): Douglas G. Ebersole, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date:                      Review results:                     

Objective(s): To evaluate the safety and efficacy of the device. In addition to achieving this objective, the study will supplement the growing body of knowledge concerning the procedure, assisting physicians with some of its technical aspects, aiding them in selecting candidates most likely to benefit from the procedure, and providing them with comprehensive data to use in comparing this form of therapy for coronary artery disease to the presently available alternatives.

Technical Approach: Patient selection, risk analysis and specifics are outlined in protocol.

Progress: We were notified by Endosonics that there is a problem with the balloon. They requested that this study be placed on hold status.

# Detail Summary Sheet

Date: 9 Aug 94 Protocol Number: C-93-126 Status: Completed

Title: Patterns of Intraventricular Flow During Isovolumic Relaxation During Normal Excitation and Right Ventricular Pacing Under Different Loading Conditions...

Start date: Aug 93	Estimated completion date: Feb 94
Principal Investigator: Robert W. Price, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s): John W. McClure, M.D. Joe M. Moody, Jr., M.D. Bernard J. Rubal, Ph.D.
Key Words:	
Cumulative MEDCASE cost: N/A	Estimated cumulative OMA cost: N/A

Number of subjects enrolled during reporting period: 8  
Total number of subjects enrolled to date: 9  
Periodic review date: Review results:

Objective(s): To characterize intraventricular flow patterns by Doppler echocardiography during normal activation, right ventricular pacing, and altered loading conditions.

Technical Approach: The study will include 30 patients who have had a permanent transvenous pacemaker placed, either a right ventricular or a dual chamber leads for established clinical indications. Volunteers for this study will be chosen from patients in the Pacemaker Clinic who meet criteria given in protocol.

Progress: Recently enrolled 2nd and 3rd subjects. Will be studying 2-3 per week until pool is exhausted. Have seen the expected effect in each patient studied so far. Study has been completed

# Detail Summary Sheet

Date: 25 Aug 94      Protocol Number: C-93-129      Status: Ongoing

Title: A Phase II Study of MGBG in Patients with Hormone Refractory Prostate Cancer to Determine Clinical Benefit

Start date: 21 Sep 93	Estimated completion date:
Principal Investigator: Howard A. Burris, M.D.	Facility: UTHSCSA; CTCofSA; & Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Suzanne M. Fields Daniel D. Von Hoff, M.D. Geoffrey Weiss, M.D. John R. Eckardt, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2  
Total number of subjects enrolled to date: 2  
Periodic review date: 31 Dec 93      Review results: Continue

Objective(s): To assess the clinical benefit of intravenous MGBG in patients with hormone refractory prostate cancer (HRPC) as measured by time to disease progression, Karnofsky performance status, and pain palliation.  
To determine the objective response rate of intravenous MGBG in those patients with HRPC and measurable disease.  
To evaluate the qualitative and quantitative toxicities of intravenous MGBG in patients with HRPC.

Technical Approach: Patient eligibility, treatment plan, drug administration, etc, covered in protocol.

Progress: Accrual of patients temporarily halted due to toxicity (mucositis). Enrollment has resumed on a modified dose schedule with pharmacokinetics (PK) being collected.

# Detail Summary Sheet

Date: 25 Aug 94      Protocol Number: C-93-130      Status: Completed

Title: Phase I Trial of Escalating Doses of Continuous Infusion Topotecan followed by Etoposide

Start date: 22 Sep 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Timothy O'Rourke, M.D. Terry Jenkins, M.D. Patrick Cobb, M.D. David A. Rinaldi, M.D. Ralph F. Heaven, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:
Number of subjects enrolled during reporting period: 0	
Total number of subjects enrolled to date: 3	
Periodic review date: 31 Dec 93      Review results:	

Objective(s): To determine the maximal tolerated dose of the combination of the Topoisomerase I and II inhibitors topotecan and etoposide. To determine the qualitative and quantitative toxicities of topotecan and etoposide on this schedule. To determine the recommended dose for topotecan and etoposide on this schedule for Phase II trials. To collect information about antitumor affects of topotecan and etoposide on this schedule.

Technical Approach: Accrual is complete and the objectives of the trial have been met. Dose limiting toxicities centered around myelosuppression, both neutropenia and thrombocytopenia. Objective responses were observed in patients with non-small cell lung cancer, gastric, colon and ovarian cancer. Phase II trials with this combination are being planned.

Progress: Accrual is complete and the objectives of the trial have been met. Dose limiting toxicities centered around myelosuppression, both neutropenia and thrombocytopenia. Objective responses were observed in patients with non-small cell lung cancer, gastric, colon, and ovarian cancer. Phase II trials with this combination are being planned.

# Detail Summary Sheet

Date: 25 Aug 94 Protocol Number: C-93-131 Status: Terminated

Title: Phase III Trial of rhu GM-CSF in Patients with Febrile Neutropenia Following Cancer Chemotherapy

Start date: 22 Sep 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 2  
Periodic review date: 31 Dec 93 Review results:

Objective(s): To evaluate the effect of rhu GM-CSF on days from initiation of study medication to the first of three consecutive measurements of ANC > 500 cells/mm<sup>3</sup> and temperature < 38.0°C.

Technical Approach: Study design, patient eligibility, study drugs, and specifics are outlined in protocol.

Progress: The study was closed due to poor accrual; some doubt exists as to whether a study design such as this is still practical (a growth factor vs placebo). A total of 24 patients were enrolled at all sites and a brief publication will be prepared.



# Detail Summary Sheet

Date: 25 Aug 94      Protocol Number: C-93-132      Status: Terminated

Title: A Safety, Antiemetic Efficacy and Pharmacokinetic Study of Single Dose IV RS-25259-197 in Cisplatin-Naive Cancer Patients Receiving High-dose Cisplatin...

Start date: 23 Sep 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: UTHSCSA Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 31 Dec 93      Review results: Continue

Objective(s): To determine the lowest dose of RS-25259 that produces complete control of emesis in at least 7 of 10 cancer patients receiving high-dose cisplatin.

To determine the maximum dose at which at least 4 of 5 patients receiving high-dose cisplatin do not suffer significant adverse events, and the minimum dose at which at least 4 of 5 patients have 2 or fewer emetic episodes in 24 hours (complete or major response).

To study the pharmacokinetics of single IV doses of RS-25259 in this patient population.

Technical Approach: Selection of patients, study medication/design, etc., are outlined in protocol.

Progress: Concerns regarding toxicology studies and the role for this agent has led the sponsor to discontinue all clinical trials with this agent. No patients were enrolled at BAMC.

# Detail Summary Sheet

Date: 25 Aug 94      Protocol Number: C-93-133      Status: Ongoing

Title: Phase II Trial of RP 56976 in Patients with Cholangiocarcinoma

Start date: 24 Sep 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Patrick W. Cobb, M.D. John R. Eckardt, M.D. Suzanne Fields, Pharm.D. Stephen Kalter, M.D. John G. Kuhn, Pharm.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 31 Dec 93      Review results: Continue

Objective(s): To assess whether taxotere given as an every three week intravenous infusion procedures objective clinical responses in patients with cholangiocarcinoma.

To assess the clinical and laboratory toxicities as well as patient tolerance of this dose/schedule of intravenous taxotere.

Technical Approach: Design, dose regimen, number and selection of patients, and other specifics are outlined in protocol.

Progress: Prioritization of resources has led the sponsor to not open this trial yet. Plans will exist for the conduct of this study in the future.

# Detail Summary Sheet

Date: 25 Aug 94      Protocol Number: C-93-134      Status: Terminated

Title: Prospective Correlative Clinical Trial of Response to Taxol in a Newly Developed Chemoresponse Assay Versus Clinical Response to Taxol in Patients with Ovarian Cancer

Start date: 27 Sep 93	Estimated completion date: 12/94
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 31 Dec 93      Review results: Continue

Objective(s): To conduct a prospective correlative clinical trial of the newly developed ChemoResponse Assay in patients with ovarian cancer. This clinical trial should definitely answer the question as to whether the ChemoResponse Assay has applications in the care of patients with ovarian cancer.

Technical Approach: Patient eligibility, overall trial design, study calendar, statistical considerations and other specifics are covered in protocol.

Progress: Trial is now open for accrual - no patients enrolled to date.

# Detail Summary Sheet

Date: 25 Aug 94      Protocol Number: C-93-135      Status: Terminated

Title: Dose Ranging, Randomized, Multicenter Study of Synercid (RP57669/RP54476) Vs. Vancomycin in the Treatment of Central Catheter-Related Gram-Positive Bacteremia

Start date: 27 Sep 93	Estimated completion date: Jun 94
Principal Investigator: Howard A. Burris, III, M.D.	Facility: UTHSCSA; CTCofSA; Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Karen Bowen, M.D. Patrick W. Cobb, M.D. Gail Eckhardt, M.D. Stephen Kalter, M.D. Jim Koeller, M.S.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 0  
Periodic review date: 31 Dec 93      Review results: \_\_\_\_\_

Objective(s): To evaluate the efficacy and safety of two different dosing regimens of Synercid compared with vancomycin hydrochloride (Vancocin HCl Lilly) when administered for 5 to 14 days in the treatment of patients with central catheter-related Gram-positive bacteremia.

Technical Approach: Patient definition, plan of the study, clinical and laboratory procedures and detailed specifics outlined in protocol.

Progress: This study was abandoned by the sponsor after a total of approximately 30 patients were enrolled at all institution. The Food and Drug Administration and the sponsor decided to alter the design in such a way that a new trial will be initiated. Our participation in additional studies remain to be determined. Those atients will be compiled with the other patients for purposes of a manuscript.

# Detail Summary Sheet

Date: 25 Aug 94      Protocol Number: C-93-136      Status: Completed

Title: Phase II Trial of RP 5676 in Patients with Advanced Epithelial Ovarian Cancer Refractory to Treatment with Cisplatin and/or Carboplatin Chemotherapy

Start date: 27 Sep 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:
Number of subjects enrolled during reporting period: 0	
Total number of subjects enrolled to date: 0	
Periodic review date: 31 Dec 93      Review results:	

Objective(s): To estimate the major objective response rate and duration of response of RP 56976 in patients with epithelial ovarian cancer refractory to platinum based chemotherapy.  
To determine the qualitative and quantitative toxicity and reversibility of toxicity of RP 5697 administered as an intravenous infusion over one hour every 21 days.

Technical Approach: Patient eligibility, plan of the study, efficacy and safety measurements, etc, are outlined in protocol.

Progress: Excellent activity was observed with Taxotere, however, with data supporting frontline use of taxol and cisplatin in this disease, the patient population for this trial disappeared. This study is thus closed, with alternative trials of Taxotere in ovarian cancer being planned. Our results will be combined with those of M.D. Anderson for purposes of a manuscript.

# Detail Summary Sheet

Date: 25 Aug 94      Protocol Number: C-93-137      Status: Completed

Title: A Phase II Trial of CPT-11 in Patients with Metastatic Colorectal Carcinoma -

Start date: 30 Sep 93	Estimated completion date: Jan 94
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 8  
 Total number of subjects enrolled to date: 8  
 Periodic review date: 31 Dec 93      Review results: Continue

Objective(s): The primary objective of this study is to estimate the antitumor activity (response rate) of CPT-11 in patients with metastatic colorectal carcinoma that has recurred following 5-FU-based therapy. The secondary objectives of this study are to evaluate the onset and duration of antitumor responses and to evaluate the qualitative and quantitative toxicities of CPT-11.

Technical Approach: Drug information, background/rationale and specifics outlined in protocol.

Progress: A total of 48 patients were placed on this trial in San Antonio. A 24% objective response rate was observed, with trends toward improved survival noted as well. The results were presented at the ASCO meeting in Dallas, TX, May 94. A manuscript draft has been completed, and should be submitted in the near future.

# Detail Summary Sheet

Date: 1 Dec 94      Protocol Number: C-94-02      Status: Ongoing

Title: Twenty-four Hour Heart Rate Variability and Intravascular Volume: Are They Abnormal in Young Active Duty Soldiers with Tilt Induced Syncope?

Start date: 18 Oct 93	Estimated completion date:
Principal Investigator: Robert Rudolphi, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s): David M. Mego, M.D. Bernie Rubal, Ph.D. LuAnn Wellford, M.D.
Key Words: Tilt Induced Syncope, Heart rate variability (HRV)	
Cumulative MEDCASE cost: .00	Estimated cumulative OMA cost: 
Number of subjects enrolled during reporting period: _____	
Total number of subjects enrolled to date: _____	
Periodic review date: _____ Review results: _____	

Objective(s): This investigation hopes to definitively determine if heart rate variability (HRV), specifically the parasympathetic component, is greater in young people with tilt induced neurally mediated syncope (NMS). Also, plasma volume prior to tilt testing will be assessed to determine if NMS patients have lower baseline intravascular volume compared to normal controls.

Technical Approach: Patient criteria, heart rate variability, tilt test, plasma volume, statistical analysis and further details included in protocol.

Progress: Six patients enrolled, study ongoing.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-04                      Status: Ongoing

Title: Growth of Human Basal Cell Carcinoma Cells in Defined Medium and Study of Their Growth and Immunologic Characteristics

Start date: 20 Oct 93	Estimated completion date:
Principal Investigator: Lawrence Anderson, M.D.	Facility: Wilford Hall AFMC & Brooke Army Medical Center, Texas
Department/Service: Medicine/Dermatology	Associate Investigator(s): William J. Grabski, M.D. Ronald E. Grimwood, M.D.
Key Words: keratinocyte growth medium, epidermal growth factor, basal cell carcinoma, tissue culture	
Cumulative MEDCASE cost: None	Estimated cumulative OMA cost: None
Number of subjects enrolled during reporting period: 6	
Total number of subjects enrolled to date: 6	
Periodic review date:                      Review results:	

Objective(s): The growth and study of basal cell carcinoma cells in culture.

Technical Approach: The defined medium for basal cell growth will consist of keratinocyte growth medium complete with epidermal growth factor, bovine pituitary extract, insulin, hydrocortisone and anti-microbial agents. This is a modified MCDB 153 formulation that is serum free and comes augmented with growth factors as stated above. Tissue for culture will be obtained from the Department of Dermatology at Wilford Hall MC and BAMC which will have been collected during a normal surgical procedure and will not subject the patient to any additional procedures. Further specifics outlined in protocol.

Progress: Preliminary growth of basal cell carcinoma in a defined medium has been successful. Success was obtained with the morphea type of basal cell carcinoma, whereas the results with the other subtypes of tumor were less encouraging. A collagen matrix preparation appears to be the best tissue culture medium. Unfortunately, the cells did not successfully pass in subsequent culture. Continued study of determining the best culturing techniques is planned.



# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-07                      Status: Completed

Title: A Phase I Trial of 2-Chlorodeoxyadenosine by 5-Day Continuous Intravenous Infusion

Start date:	Estimated completion date:
Principal Investigator: Howard A. Burris, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Timothy O'Rourke, M.D. Terry Jenkins, M.D. Patrick Cobb, M.D. David A. Rinaldi, M.D. Ralph F. Heaven, M.D.
Key Words: pharmacokinetic behavior, 2-chlorodeoxyadenosine (2-CDA), peripheral blood lymphocyte	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To characterize the dose-limiting toxicity and to estimate the maximum tolerated dosage of 2-chlorodeoxyadenosine in patients with advanced cancer. To identify any preliminary evidence of anticancer activity in treated patients. To estimate the human plasma pharmacokinetic behavior of 2-CDA in patients treated on a 5-day continuous infusion schedule. To monitor patients for alterations in peripheral blood lymphocyte number and phenotype induced by 2-CDA infusion.

Technical Approach: Preclinical/clinical toxicity studies, drug information, eligibility criteria, treatment plan and other specifics are outlined in protocol.

Progress: Accrual has been completed. Thrombocytopenia is the Dose Limiting Toxicity (DLT). No solid tumor antineoplastic effects were observed. A manuscript has been submitted to Investigational New Drugs.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-08                      Status: Ongoing

Title: Elimination of Extrachromosomal DNA from Ovarian Cancer Patients' Tumors with Hydroxyurea Treatment

Start date:	Estimated completion date:
Principal Investigator: Howard A. Burris, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Timothy O'Rourke, M.D. Terry Jenkins, M.D. Patrick Cobb, M.D. David A. Rinaldi, M.D. Ralph F. Heaven, M.D.
Key Words: Extrachromosomal DNA, Hydroxyurea, refractory ovarian cancer	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine if hydroxyurea can decrease the amount of extrachromosomal DNA in patients' ovarian cancer cells. To determine if hydroxyurea can decrease the number of ovarian cancer cells in patients' malignant ascites. To determine the amount of transport of hydroxyurea into malignant ascites of patients with ovarian cancer. To determine if hydroxyurea induces responses in patients with advanced refractory ovarian cancer.

Technical Approach: Patient eligibility criteria, descriptive factors, treatment plan and detailed specifics are outlined in protocol.

Progress: Accrual has been slow but preliminary results are encouraging. Ascites has been ameliorated and extrachromosomal LDNA counts reduced with the use of hydrea.

# Detail Summary Sheet

Date: 1 Dec 94      Protocol Number: C-94-15      Status: Terminated

Title: A Phase I Study of PD115934 Administered on Days 1 and 8 Every Twenty-Eight Days to Patients with Refractory Solid Tumors

Start date: Sep 93	Estimated completion date:
Principal Investigator: Howard A. Burris, M.D.	Facility: UTHSCSA & Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): John R. Eckardt, M.D. Daniel D. Von Hoff, M.D. David A. Rinaldi, M.D.
Key Words: Antitumor activity	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine the maximum tolerated dose of PD115934 when administered intravenously daily over 2 hours on days one and eight repeated every twenty-eight days. To describe the toxicity of PD115934 when administered intravenously, on days 1 and 8 ever 28 days. To describe the pharmacokinetics of PD115934 when administered intravenously on this schedule. To evaluate any anti-tumor activity observed.

Technical Approach: Inclusion/exclusion criteria, design, dosage, treatment period and other specifics are outlined in protocol.

Progress: The National Cancer Institute has decided not to pursue this schedule of drug. No patients were registered.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-16                      Status: Completed

Title: A Randomized, Double-Blind, Multicenter Trial Comparing 10 Days of Oral Therapy with CP-99,219 (100 mg or 300 mg Daily) or Ofloxacin (800 mg Daily) for the Treatment of Acute Exacerbation of Chronic Bronchitis

Start date: Dec 93	Estimated completion date:
Principal Investigator: Mark D. Peacock, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Pulmonary Disease	Associate Investigator(s):
Key Words: Acute exacerbation, Ofloxacin	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 3  
 Total number of subjects enrolled to date: 3  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To compare the safety and efficacy of two doses of CP-99.219 and ofloxacin in the treatment of patients with acute exacerbations of chronic bronchitis.

Technical Approach: Subject selection criteria, plan and design, study therapy and further specifics are outlined in protocol.

Progress: Enrollment into this study has been terminated by Pfizer. This institution enrolled three patients, two of which had moderate but temporary site effects from the antibiotics.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-19                      Status: Ongoing

Title: Time-Frequency Analysis of Phonocardiograms: A Study of Prosthetic Heart Valve Sounds

Start date: Dec 93	Estimated completion date:
Principal Investigator: J. Mark Moody, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s): James R. Bulgrin, BS-EE Bernard J. Rubal, Ph.D. Terry D. Bauch, M.D. T. E. Posch, MS-EE
Key Words: Phonocardiograms (PCG), Prosthetic Heart valve	
Cumulative MEDCASE cost: .00	Estimated cumulative OMA cost: .00

Number of subjects enrolled during reporting period: Info as of 3 Dec 93

Total number of subjects enrolled to date: Over 5,000 = 6,609

Periodic review date: 2 Aug 94      Review results: See below

Objective(s): To evaluate an inexpensive, non-invasive method of analyzing phonocardiograms (PCGs) in order to longitudinally assess evolving structural and physiologic problems associated with implanted heart valve prostheses.

Technical Approach: This is a descriptive study intended to characterize the time-frequency distributions, via several analytical techniques, of PCGs from as many patients with prosthetic heart valves as possible, and following these patients over a significantly long interval. Further details in protocol.

Progress: Still in processing of establishing technology to acquire, analyze and display signals: We have acquired data on two patients, neither satisfactory.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-22                      Status: Ongoing

Title: Time-Frequency Analysis of ECG in Patients Post-Myocardial Infarction and at Risk for Sudden Death

Start date: Nov 93	Estimated completion date:
Principal Investigator: Thien M. Do, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s): Bernard J. Rubal, Ph.D. James R. Bulgrin, BSEE T. E. Posch, MS-EE, Hughes Aircraft
Key Words: Post-myocardial infarction, inducible ventricular tachycardia	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 20  
Total number of subjects enrolled to date: 20  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To assess the clinical utility of time-frequency analysis of the ECGs in sudden death survivors and patients post myocardial infarction and with inducible ventricular tachycardia.

Technical Approach: Inclusion/exclusion criteria, methods for obtaining TFD and signal averaged ECGs, etc. covered in protocol.

Progress: Sent to California for analysis. Awaiting new software in order to do analysis here.

# Detail Summary Sheet

Date: 1 Dec 94      Protocol Number: C-94-23      Status: Ongoing

Title: A Phase I Study of AM-285 Administered Via the Intraperitoneal Route in Patients with Intraperitoneal Predominantly Tumoral Disease

Start date: Dec 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words: Intraperitoneal route, pharmacokinetic profile	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Review results:

Objective(s): To determine the safety and tolerance of AM-285 at doses ranging from 10 to 150 mg/kg administered by the intraperitoneal route. To determine the pharmacokinetic profile of AM-285 when administered via this route/schedule.

Technical Approach: Patient selection, study synopsis (treatment program), and other specifics included in protocol.

Progress: This study is on hold pending deliberations with the sponsor. It is unclear if intraperitoneal administration is a worthwhile route to pursue.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-24                      Status: Ongoing

Title: A Phase I Trial of LY231514 Administered as a Bolus Given Intravenously Every 21 Days

Start date: Sep 93	Estimated completion date: 1 Oct 94
Principal Investigator: David A. Rinaldi, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Daniel D. Von Hoff, M.D. Howard Burris, III, M.D. Timothy J. O'Rourke Patrick Cobb, M.D. Enriquez Perez, M.D., et al
Key Words: bolus infusion, pharmacokinetics/pharmacodynamics LY231514, cancer	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 8  
Total number of subjects enrolled to date: 8  
Periodic review date: Review results:

Objective(s): To determine the maximum tolerated dose of LY231514 administered as a bolus infusion given every 21 days. To determine the qualitative and quantitative toxicities of LY231514 on this schedule. To determine the recommended dose of LY231514 on this schedule for Phase II trials. To characterize the pharmacokinetics/pharmacodynamics of LY231514. To collect information about the antitumor effects of LY231514.

Technical Approach: Study population/criteria, dosage administration, efficacy criteria and detailed specifics outlined in protocol.

Progress: Eight patients have been treated on this protocol at BAMC. The dosages have been escalated from 50 mg/m<sup>2</sup> to 700 mg/m<sup>2</sup>. Currently patients are being accrued at 60 mg/m<sup>2</sup>, which is anticipated to be the recommended phase II dose. The dose limiting toxicities are neutropenia, thrombocytopenia, mucositis and malaise at the 700 mg/m<sup>2</sup> dose level. Pharmacokinetics have been obtained in all patients. There have been no major antitumor responses to date, however, one patient with advanced colon cancer exhibited a minor response.



# Detail Summary Sheet

Date: 1 Dec 94 Protocol Number: C-94-25 Status: Ongoing

Title: A Phase I/II Dose-Escalating Study of Intravenously Administered Tirapazamine (WIN 59075) in Combination with Cisplatin, in Patients with Non-Small Cell Lung Cancer

Start date: Sep 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: CTRC & Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Gladys I. Rodriguez, M.D.
Key Words: Tirapazimine, Cisplatin, maximum tolerated dose (MTD)	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2  
Total number of subjects enrolled to date: 2  
Periodic review date: Review results:

Objective(s): To determine the safety and side effects of tirapazamine, when administered IV in combination with cisplatin, by monitoring patients for adverse effects through clinical observations and laboratory parameters. To determine the pharmacokinetics of tirapazamine and cisplatin, when administered IV in this combination with cisplatin, through periodic sampling of the patients' body fluids. To estimate the maximum tolerated dose (MTD) of tirapazamine, when administered IV in combination with cisplatin, by evaluating all therapy related adverse events. To assess the effects of tirapazamine, when administered IV in combination with cisplatin, on tumor tissues through tumor measurements.

Technical Approach: Study design, inclusion/exclusion criteria, study plan, dosing procedure and specifics outlined in protocol.

Progress: Accrual has gone well and numerous objective responses have been observed. The treatment has been well tolerated except for delayed nausea and vomiting and some mild electrolyte abnormalities. A Phase II trial with this combination will be conducted once the Maximum Tolerated Dose (MTD) has been established.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-26                      Status: Ongoing

Title: A Rising Dose-Level, Safety Tolerability and Pharmacokinetic Phase I Study of GII47211 Administered Daily by Injection for Five (5) Consecutive Days to Patients with Cancer

Start date: Dec 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility:        CTRC & Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Timothy O'Rourke, M.D. Terry Jenkins, M.D. Patrick Cobb, M.D. David A. Rinaldi, M.D.
Key Words: Rising dose-level, safety tolerability, anti-tumor activity	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 3  
Total number of subjects enrolled to date: 3  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1. Evaluate safety and tolerability of GII47211 within the dose range of 0.3mg/M<sup>2</sup>/day to the maximum tolerable dose when administered by daily injection for five consecutive days; 2. Evaluate the pharmacokinetics of GII47211 in patients with cancer; 3. Evaluate the dose-related tolerability of GII47211, with emphasis on correlating hematologic effect with GII47211 plasma concentrations; 4. Assess the pharmacodynamics of GII47211 with hematologic toxicity as a dynamic end point and; 5. Assess, in a preliminary manner, early anti-tumor activity.

Technical Approach: Patient selection, study procedure, data collection/analysis and detailed specifics given in protocol.

Progress: This phase I trial nears completion. Toxicities have centered around myelosuppression including both neutropenia and thrombocytopenia; non-hematologic toxicity has been mild. No antitumor activity observed to date.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-27                      Status: Ongoing

Title: Percutaneous Transluminal Coronary Angioplasty Versus Coronary Stenting of De Novo Saphenous Vein Bypass Grafts

Start date: 30 Dec 93	Estimated completion date:
Principal Investigator: William T. Wright, M.D.	Facility: UTHSCSA & Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s): Douglas G. Ebersole, M.D.
Key Words: De Novo, saphenous vein bypass grafts, balloon angioplasty	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 6  
Total number of subjects enrolled to date: 6  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): The placement of expandable stents in saphenous vein grafts has shown initial promising results in terms of lower rates of restenosis compared with balloon angioplasty. This is a multicenter, randomized study designed to further examine this subject. Patients with de novo stenoses of saphenous vein grafts will be assigned randomly to either routine angioplasty or the placement of a coronary stent, (supplied by Johnson and Johnson Interventional Systems, Co). Restenosis will be evaluated by routine clinical follow-up, including exercise testing and repeat angiography when indicated. Analysis of angiography and data will be performed by a core lab. BAMC will enroll 15-30 patients, in conjunction with the Univ of Texas Health Science Center at San Antonio Cardiology Service.

Technical Approach: Study population, inclusion/exclusion criteria, materials/methods and further specifics outlined in protocol.

Progress: Total enrollment = 15/total BAMC enrollment = 6:  
1 Death unrelated to stent  
2 of 3 stent patients restenosed  
3 of 3 PTCA patients free of symptoms continuing to enroll patients who meet criteria; monitoring clinical followup.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-34                      Status: Ongoing

Title: Comparison of Fluorescent Bronchoscopy to White-Light Bronchoscopy in Detecting Lung Carcinoma

Start date: 21 Jan 94	Estimated completion date:
Principal Investigator: Gregg T. Anders, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Pulmonary Disease/Crit Care	Associate Investigator(s): H. M. Blanton, M.D.
Key Words: Fluorescent Bronchoscopy, White-light bronchoscopy	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 1  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine any statistically significant increase in lung cancer diagnosis using fluorescent bronchoscopy as compared to white-light bronchoscopy performed on the same period. Patients will be selected from three groups for whom the medical literature has suggested a higher than usual rate of occurrence (or, in some cases, recurrence) of bronchogenic carcinoma-- patients in whom lung cancer has been resected; patients diagnosed with head and neck cancer; and patients who smoke more than two packs of cigarettes daily.

Technical Approach: Patients will serve as their own controls via the white-light bronchoscopy. They will be selected from one of the following groups: 1. Patients with Stage I resected lung cancer without evidence of metastasis, referred from the Thoracic Surgery service or the Medical Oncology Clinic to the Pulmonary clinic, BAMC; 2. Patients with surgically resected head and neck cancer without evidence of metastasis at the time of initial diagnosis, referred from the Otolaryngology Clinic; 3. Patients referred to BAMC Pulmonary Service of the Smoking Cessation Clinic who are currently smoking more than two packs of cigarettes per day with symptoms of cough or dyspnea. Inclusion/exclusion criteria details included in protocol.

Progress: One patient has been enrolled thus far - equipment was not on-line prior to 15 Sep 94.

# Detail Summary Sheet

Date: 1 Dec 94 Protocol Number: C-94-36 Status: Ongoing

Title: A Phase I Trial of Losoxantrone in Combination with Paclitaxel in Patients with Refractory Malignancies

Start date: 24 Jan 94	Estimated completion date:
Principal Investigator: Patrick Cobb, M.D.	Facility: VA, CTCR, St. Luke's Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Timothy O'Rourke, M.D. Terry Jenkins, M.D. Howard Burris, M.D. David A. Rinaldi, M.D. Ralph F. Heaven, M.D.
Key Words: Losoxantrone, Paclitaxel, Dose limiting toxicities (DLTs), qualitative/quantitative toxicities	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4  
Total number of subjects enrolled to date: 4  
Periodic review date: Review results:

Objective(s): 1. To determine the maximum tolerated dose (MTD) and the recommended dose (RD) for subsequent Phase II trials of losoxantrone in combination with paclitaxel. 2. To determine the dose limiting toxicities (DLTs) of losoxantrone in combination with paclitaxel, including qualitative and quantitative toxicities, and to define their duration and reversibility. 3. To evaluate the pharmacokinetics of losoxantrone and paclitaxel when given in combination. 4. To evaluate the antitumor activity of losoxantrone plus paclitaxel. Study design, duration, study population, medications, etc., outlined in protocol.

Technical Approach: Approximately six months will elapse from the enrollment of the first patient until the enrollment of the last patient. Enrollment will continue until the maximum tolerated dose is identified.

Progress: The initial dose of losoxantrone 40mg/m<sup>2</sup> and paclitaxel 135 mg/m<sup>2</sup> given over 24 and 3 hours had unacceptable neutropenia as its toxicity. G-CSF was added to the regimen for prevention of neutropenic fevers. Patients then tolerated the dose level well and further dose escalations are ongoing.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-37                      Status: Ongoing

Title: The Effect of h Corticotrophin-Releasing Factor on Peritumoral Brain Edema, A Pilot Study

Start date: 25 Jan 94	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: UTHSCSA, CTRC Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Timothy O'Rourke, M.D. Terry Jenkins, M.D. Patrick Cobb, M.D. David A. Rinaldi, M.D. Ralph F. Heaven, M.D.
Key Words: h-Corticotrophin-Releasing Factor, Peritumoral Brain Edema	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: \_\_\_\_\_ Review results: Continue

Objective(s): 1. To evaluate the tolerability of hcorticotropin-releasing factor administered intravenously in ascending doses to patients with peritumoral brain edema. 2. To determine if hcorticotropin-releasing factor produces any reduction in peritumoral brain edema as determined by magnetic resonance imaging.

Technical Approach: Materials/methods, study population, study design, study plan and management, etc, outlined in protocol.

Progress: This trial has recently opened with 5 patients enrolled to date. No toxicity and good efficacy has been observed in this first cohort.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-38                      Status: Ongoing

Title: Phase 2 Double-Blind, Randomized Study of Recombinant Human Interleukin 11 (NEUMEGA rhIL-11 Growth Factor) at Doses of 25 and 50 mcg/kg/d vs Placebo in Adult Cancer Patients with Severe Thrombocytopenia Due to Chemotherapy

Start date: 27 Jan 94	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: VA, CTRC, St Luke's Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Timothy O'Rourke, M.D. Terry Jenkins, M.D. Patrick Cobb, M.D. David A. Rinaldi, M.D. Ralph F. Heaven, M.D.
Key Words: rhIL-11 Growth Factor, Placebo, Thrombocytopenia, ameliorating	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To compare the activity of two doses (25 and 50 mcg/kg/d) of recombinant human interleukin 11 (NEUMEGA™ rhIL-11 Growth Factor) with a placebo in ameliorating severe chemotherapy-induced thrombocytopenia in cancer patients receiving a variety of chemotherapy regimens and to gain additional information regarding the safety of rhIL-11 administration at the specified doses. Also to assess whether IL-11 antibodies are produced and to measure IL-11 serum levels.

Technical Approach: Design, eligibility, treatment plan, adverse experiences, statistical analysis, etc, outlined in protocol.

Progress: Accrual has gone poorly at all sites. A very specific and difficult to find population is being studied. Attempts at enhancing accrual are being made.

# Detail Summary Sheet

Date: 1 Dec 94      Protocol Number: C-94-39      Status: Ongoing

Title: Phase I Clinical and Pharmacokinetic Evaluation of LY 295501  
Administered Orally on a Weekly Schedule in Patients with Metastatic Cancer

Start date: 27 Jan 94	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: UTHSCSA, CTRC Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Timothy O'Rourke, M.D. Terry Jenkins, M.D. Patrick Cobb, M.D. David A. Rinaldi, M.D. Ralph F. Heaven, M.D.
Key Words: Metastatic, Maximum tolerated dose, anti-tumor effects	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:
Number of subjects enrolled during reporting period: 5	
Total number of subjects enrolled to date: 5	
Periodic review date: Review results: Continue	

Objective(s): Primary objective of this study is to determine the maximum tolerated dose (MTD) of LY295501 as a single dose given once weekly for 3 weeks every 4 weeks in patients with metastatic cancer. Secondary objectives are to determine the qualitative and quantitative toxicities of LY295501 as a single dose given once weekly for 3 weeks every 4 weeks in patients with metastatic cancer, to determine the recommended dose for LY295501 to be used for initial therapeutic trials, to determine the basic pharmacokinetics of LY295501 by study of plasma and urinary levels of the agent in humans, and to collect information about the antitumor effects of LY295501.

Technical Approach: Study design, control, population, patient assignment, dosage administration, etc., outlined in protocol.

Progress: Accrual has gone well with minimal toxicity observed to date.



# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-42                      Status: Ongoing

Title: A Phase I Trial of Paclitaxel; (IVX-T-101) Administered as a Three-Hour Infusion in Patients with Refractory Non-Small Cell Lung Cancer

Start date: 28 Jan 94	Estimated completion date:
Principal Investigator: Patrick W. Cobb, M.D. Center, Texas	Facility: UTHSCSA, CTRC Brooke Army Medical
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Timothy O'Rourke, M.D.
Key Words: Paclitaxel, non-small cell	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 0  
Periodic review date: Review results:

Objective(s): 1. To determine the maximal tolerated dose of paclitaxel given as a 3-hour infusion every 21 days. 2. To determine the qualitative and quantitative toxicities of paclitaxel given as a 3-hour infusion every 21 days. 3. To characterize the pharmacokinetics of paclitaxel administered as a 3-hour infusion. 4. To determine the recommended dose of paclitaxel given as a 3-hour infusion every 21 days to be used in Phase II trials. 5. To collect information about the antitumor effects of paclitaxel in patients with Non-Small Cell Lung Cancer.

Technical Approach: Drug info, eligibility criteria, treatment plan, pharmacokinetics, etc., outlined in protocol.

Progress: Due to problems in drug manufacturing, this trial has not accrued patients. We expect to begin enrollment within the next few months.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-43                      Status: Ongoing

Title: Comparison of Newer Doppler-Echocardiographic Methods for the Quantification of Mitral Regurgitation

Start date: 4 Feb 94	Estimated completion date:
Principal Investigator: Jerry D. Champ, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s):
Key Words: Mitral regurgitant volume, control velocity,	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 16  
 Total number of subjects enrolled to date: 16  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To compare the mitral regurgitant volume as determined by three quantitative Doppler techniques -- 1) a volumetric method utilizing Doppler-derived stroke volume in the left ventricular outflow tract and mitral annulus; 2) a technique involving color flow imaging of the flow convergence region; 3) a new method involving the product of the mitral regurgitant color flow jet area and the mitral regurgitant time velocity integral.

Technical Approach: The quantification of mitral regurgitation has been a long-standing problem of some clinical importance. Difficulties in quantifying the regurgitant flow continue despite the advent of Doppler echocardiographic methods for measuring the severity of mitral regurgitation. Several newer techniques have been advanced in the literature addressing this problem. This study compares the accuracy and ease of use of these techniques for calculating regurgitant volume with a volumetric Doppler method in a clinical setting.

Progress: Preliminary statistical analysis on 11 patients reveals a correlation coefficient for the area method of  $r=0.83$  and that for the flow convergence method of  $r=0.49$ .

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-44                      Status: Ongoing

Title: Effect of Intravenous Erythromycin on Gastric Emptying in Patients with Billroth I or Billroth II Anastomosis

Start date: 1 Feb 94	Estimated completion date:
Principal Investigator: Shailesh C. Kadakia, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s): Neil Katz, M.D. Rashmikan Shah, M.D. Vimal Sodhi, M.D.
Key Words: Erythromycin, Billroth I, Billroth II, anastomosis	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): The purpose of this study is to evaluate the efficacy of intravenous erythromycin on gastric emptying in patients with Billroth I and Billroth II anastomosis. The radionuclide assessed gastric emptying of a standard meal will be performed as baseline in these patients on entry into the study. On a later day, the patients will undergo repeat gastric emptying study 30 minutes after receiving a single dose of 250 mg of intravenous erythromycin. These studies will be compared to the baseline study to determine the beneficial effect of erythromycin on the gastric emptying. In addition, serum levels of motilin will be obtained during the baseline gastric emptying study and the gastric emptying study after intravenous erythromycin administration.

Technical Approach: All symptomatic adult patients (older than 18 years) who have had previous ulcer surgery wherein billroth I or Billroth II anastomosis was performed will be invited to participate in the study. These patients will be evaluated by the staff principal investigator. Patient inclusion/exclusion criteria outlined in protocol. Detailed specifics are outlined in protocol.

Progress: Since the approval date of 1 Feb 94 and 14 Sep 94 no patients have been enrolled in this study. We are currently in the process of involving an internal medicine resident or gastroenterology fellow in this study so that patients can be enrolled. We intend to continue this study and will report as soon as patients are enrolled.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-48                      Status: Completed

Title: Evaluation of Iontophoretic Administration of Lidocaine HCL 2% and 1:100,000 Epinephrine to Induce Local Anesthesia of the Skin Prior to Injection of Anesthetic for Mohs Micrographic Surgery

Start date: 15 Feb 94	Estimated completion date:
Principal Investigator: William J. Grabski, M.D.	Facility: WHMC Brooke Army Medical Center, Texas
Department/Service: Medicine/Dermatology	Associate Investigator(s): Kennard, Charles, USAF, MC
Key Words: Iontophoretic, Lidocaine HCL, Epinephrine, Mohs Micrographic, placebo	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 39  
Total number of subjects enrolled to date: 39

Periodic review date:                      Review results:                     

Objective(s): To compare the clinical efficacy of the iontophoretic administration of Lidocaine HCL 2% and 1:100,000 Epinephrine versus the administration of placebo to induce local anesthesia of the skin prior to the injection of anesthetics for Mohs Micrographic Surgery. To monitor the nature and frequency of adverse events associated with Iontophoretic administration of Lidocaine HCL 2% and 1:100,000 Epinephrine.

Technical Approach: Study design, patient selection and specifics are outlined in protocol.

Progress: We enrolled 39 patients in this study and the study was closed out in Sep 94. The results have been given to the statistician at the Iomed Co. At cursory inspection of the data the iontophoresis did not appear to be (statistically) significantly better than placebo. This data will be reviewed in depth and we will be notified of the final results. No paper has been started at this time pending final results. The Iomed Co has given a check for \$7800 via the National Kidney Foundation for use by Dermatology.

# Detail Summary Sheet

Date: 1 Dec 94      Protocol Number: C-94-49      Status: Ongoing

Title: Cell Culture to Test if MCF-7 Breast Cancer Cells in Vitro are Independent of Thyroid Hormone

Start date: Feb 94	Estimated completion date:
Principal Investigator: Gilberto Vigo, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Int Med Cl, Gen Med Svc	Associate Investigator(s): Kevin Carlin, M.D. Isidoro Chapa Albert Thomason, M.D.
Key Words: serum free medium, variable thyroid levels	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): MCF-7 an established breast cancer cell line will be grown in serum free medium with 2 million cells added to each of 4 flasks (as counted by coulter counter). Variable levels of thyroid hormone will be added to each of the 4 flasks. After a period of 10 days the cells will be counted to see if there is a statistically significant difference in the growth rate of the variable thyroid levels.

Technical Approach: MCF-7 breast cancer cells will be obtained from an established biological research firm. The cells will be at first grown in their optimum medium for several weeks until sufficient numbers are available. Then two million cells (as counted by coulter counter) will be added to each of four flasks. Serum free medium PFMR-4 from Sigma St Louis will be used as the culture medium. Details given in protocol.

Progress: Already reported to local ACP meeting, now being repeated to make sure the cells are independent of thyroid hormone.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-51                      Status: Ongoing

Title: The Effect of Tetrac and Triac Upon Murine Bladder Cancer Cells in Cell Culture

Start date: Feb 94	Estimated completion date:
Principal Investigator: Andrew Chung, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Internal Med Cl, Gen Med/Medicine	Associate Investigator(s): Kevin Carlin, M.D. Isidoro Chapa Albert Thomason, M.D.
Key Words: Tetrac/Triac, Murine bladder cancer cells, serum free medium thyroid hormone analogs, Musculus	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): Murine bladder cancer cells will be grown in serum free medium with 2 million cells added to each of 5 flasks (as counted by coulter counter). Variable levels of Tetrac and Triac (thyroid hormone analogs) will be added to each of the 5 flasks. After a period of 10 days the cells will be counted to see if there is a statistically significant difference in the growth rate with the variable Triac and Tetrac levels.

Technical Approach: Murine transitional cell carcinoma (MBT 2) cells were obtained from an in vivo bladder tumor in 1990 and have been maintained in frozen state and cell culture since. Cells have episodically undergone passage thru mice (species Musculus, strain C3H). Two million (as counted by coulter counter) of these cells will be added to each of 5 flasks. Schedule outlined in protocol.

Progress: Project has been presented to local ACP meeting, now being repeated to make sure Triac/Tetrac inhibits cancer growth.

# Detail Summary Sheet

Date: 1 Dec 94      Protocol Number: C-94-53      Status: Ongoing

Title: A Randomized Clinical Trial Evaluating Topical Vitamin E Oil in the Treatment of Chemotherapy Induced Mucositis

Start date: 14 Feb 94	Estimated completion date:
Principal Investigator: Svetislava Vukelja, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Vernon T. Lew
Key Words: Vitamin E Oil, Mucositis, high-dose chemotherapy, neoplasms	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 9  
 Total number of subjects enrolled to date: 9  
 Periodic review date: Dec 94      Review results:

Objective(s): To determine by a prospective, randomized controlled trial, the efficacy of Vitamin E in the treatment of mucositis associated with high dose chemotherapy.

Technical Approach: High dose chemotherapy with autologous stem cell support has become an increasingly popular approach for the treatment of various neoplasms. It is used commonly in many hematologic malignancies such as AML, ALL and NHL as well as in an investigational role in some solid tumors like breast cancer. The morbidity and mortality associated with this therapy however is considerable and has limited its routine use. Details including drug information, patient eligibility, treatment plan and specifics are outlined in protocol.

Progress: Collecting data.

# Detail Summary Sheet

Date: 15 Dec 94      Protocol Number: C-94-57      Status: Ongoing

Title: Blood Velocity, Valve Leaflet Flutter and Murmurs in Normal Teenagers

Start date: 14 Feb 94	Estimated completion date: Spring '98
Principal Investigator: J. Mark Moody, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s): Andrew T. Moody Sheri Y. Nottestad, M.D. Bernard J. Rubal, Ph.D.
Key Words: valve leaflet flutter, blood flow velocity	
Cumulative MEDCASE cost: .00	Estimated cumulative OMA cost: .00

Number of subjects enrolled during reporting period: 7  
Total number of subjects enrolled to date: 7  
Periodic review date: 2 Aug 94      Review results: See below

Objective(s): To examine the hypothesis that normal subjects with murmurs are more likely to have valve leaflet flutter than those without murmurs and that these subjects also have higher blood flow velocity than those without murmurs.

Technical Approach: Subject population, clinical examination, echocardiographic equipment, data analysis/statistics, etc., outlined in protocol.

Progress: We have acquired data on seven patients so far; analysis incomplete, no problems encountered except slow recruiting.



# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-59                      Status: Ongoing

Title: A Phase I Trial of Navelbine in Combination with Estramustine in Patients with Hormone Refractory Prostate Cancer

Start date: 15 Nov 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hem-Onc	Associate Investigator(s):
Key Words: Navelbine, Estramustine, Hormone Refractory Prostate CA	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 0  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine the maximally tolerated dose of Navelbine (vinorelbine tartrate) given as short intravenous injection on days 1 and 8 in combination with a fixed dose of estramustine given orally in three divided daily doses on days 1-21 with the regimen repeated every 28 days. To determine the quantitative and qualitative toxicities of the concomitant administration of Navelbine and estramustine. To determine the recommended dose for Navelbine and estramustine on this schedule.

Technical Approach: Patient Eligibility, study plan and specifics are outlined in protocol.

Progress: This study has recently been opened. No patients have been enrolled to date.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-60                      Status: Ongoing

Title: A Phase II Study to Determine the Anti-Tumor Effect of Intravenous Ilmofofisine Administered as a 120-Hour Infusion Every 21 Days to Patients with Colon Cancer

Start date: 20 Dec 93	Estimated completion date: ?
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hem-Onc	Associate Investigator(s):
Key Words: Ilmofofisine, Colon Cancer, sulfoxide, metabolite	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 1  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To assess the anti-tumor effect of a five-day (120-hr) continuous infusion if ilmofofisine administered at a dose of 300 mg/m<sup>2</sup>/day to patients with colon cancer. To assess the toxicity of ilmofofisine. To evaluate the serum concentration-time profile of ilmofofisine and the sulfoxide metabolite at steady state.

Technical Approach: Patients 18 years of age and older with cytologically or histologically confirmed colon cancer. Further specifics in protocol.  
 Exclusion criteria: Concurrent life threatening illness, inadequate renal, hepatic, or bone marrow function; performance status of 3 or 4; pregnancy.

Progress: Patient enrollment continues with an interim analysis at 20 patients.

# Detail Summary Sheet

Date: 1 Dec 94      Protocol Number: C-94-64      Status: Ongoing

Title: Double Blind, Parallel Group Exploratory Study Comparing the Efficacy and Safety of Topitriol (Topical Calcitriol) with that of Vehicle in the Protection from Chemotherapy Induced Hair Loss, in Patients with Breast Cancer

Start date: 20 Sep 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D. Texas	Facility: UTHSCSA, CTSC & Brooke Army Medical Center,
Department/Service: Medicine/Hem-Onc	Associate Investigator(s): Timothy O'Rourke, M.D. Terry Jenkins, M.D. Patrick Cobb, M.D. David A. Rinaldi, M.D. Ralph F. Heaven, M.D.
Key Words: Topitriol, hair loss, doxorubicine, Cyclophosphamide, 5- fluorouracil	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2  
Total number of subjects enrolled to date: 2  
Periodic review date: \_\_\_\_\_ Review results: Continue

Objective(s): To determine if 7 days of pre-treatment of the scalp with 0.0025% Topitriol leads to clinically significant (>50% reduction in hair loss) improvement in the alopecia associated with the use of a standard doxorubicin-containing regimen for the therapy of advanced breast cancer (CAF: Cyclophosphamide, Doxorubicin, and 5-Fluorouracil). The secondary objective is to determine if sufficient systemic absorption of Topitriol occurs with this application regimen to alter calcium metabolism in patients with advanced breast cancer.

Technical Approach: Experimental Design and Methods; Schedule of Assessments/Treatments; Patient Selection Criteria and other specifics are outlined in protocol.

Progress: Accrual to this study has recently been reinitiated. Patients will be receiving increased doses of Topitriol. Additional women with node positive breast cancer receiving adjuvant chemotherapy will be entered.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-65                      Status: Terminated

Title: A Phase I Trial and Pharmacokinetic Study of Temozolomide in Patients with Advanced Refractory Solid Tumors of Refractory Lymphoma

Start date: 20 Sep 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: UTHSCSA, CTSC & Brooke Army Medical Center, Texas
Department/Service: Medicine/Hem-Onc	Associate Investigator(s): Timothy O'Rourke, M.D. Terry Jenkins, M.D. Patrick Cobb, M.D. David A. Rinaldi, M.D. Ralph F. Heaven, M.D.
Key Words: Temozolomide, Refractory lymphoma, dose-limiting toxicity (DLT)	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To estimate the maximum tolerated dosage and the dosage for phase II trials for oral temozolomide in patients with advanced cancer and lymphoma. To characterize the dose-limiting toxicity and other toxicities of orally administered temozolomide. To estimate the plasma and urinary pharmacokinetics of temozolomide when administered orally with or without food. To identify any preliminary evidence of anticancer activity in treated patients.

Technical Approach: Preclinical and Clinical Antitumor/Toxicity Studies, drug info, eligibility criteria, treatment plan and other specifics outlined in protocol.

Progress: Terminated due to withdrawal of the protocol by the National Cancer Institute. A substitute trial sponsored by Schering Plough has been submitted to the IRB and approved (C-94-127).

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-66                      Status: Ongoing

Title: An Open Label, Multicenter, Phase I/II, Dose Escalating Tolerance and Safety Study of Glycosylated Recombinant Human Interleukin-6 (r-hIL-6) in Patients Receiving Chemotherapy"

Start date: 1 Dec 94	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D. Texas	Facility: UTHSCSA, CTSC & Brooke Army Medical Center,
Department/Service: Medicine/Hem-Onc	Associate Investigator(s): Timothy O'Rourke, M.D. Terry Jenkins, M.D. Patrick Cobb, M.D. David A. Rinaldi, M.D. Ralph F. Heaven, M.D.
Key Words: Interleukin-6 (r-hIL-6), myelosuppressive, hematopoietic, attenuated thrombocytopenia	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
Total number of subjects enrolled to date: 1  
Periodic review date: \_\_\_\_\_ Review results: Continue

Objective(s): To assess the safety and tolerance of administering repetitive daily subcutaneous doses of r-hIL-6 to patients with solid tumors before and after myelosuppressive chemotherapy. To identify for future clinical testing a safe and recommended dose and/or maximum tolerated dose of r-hIL-6 by means of cohort dose escalations. To perform study-associated laboratory based investigations which will provide insight into the biologic actions of r-hIL-6 in vivo. To perform study-associated laboratory based investigations which will provide insight into the biologic actions of r-hIL-6 in vivo. To evaluate the rate of hematopoietic recovery after myelosuppressive chemotherapy, and to determine any preliminary evidence of efficacy from r-hIL-6 which may be apparent in terms of attenuated thrombocytopenia or accelerated platelet count recovery.

## Technical Approach:

Progress: Dose escalation proceeds on this study. Good thrombopoietic effect has been observed with IL6, and good antitumor activity with the carboplatin. Toxicities have included flu-like symptoms and low grade fevers. Preliminary results were presented at the American Society of Hematology (ASH) meeting in Dec 93.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-68                      Status: Ongoing

Title: A Phase I/II Study of SDZ PSC 833 with Doxorubicin, Vincristine, Cyclophosphamide and Prednisone in Patients with Refractory or Relapsed Non-Hodgkin's Lymphoma

Start date: 20 Sep 93	Estimated completion date:
Principal Investigator: Patrick W. Cobb, M.D.	Facility: UTHSCSA, CTSC & Brooke Army Medical Center, Texas
Department/Service: Medicine/Hem-Onc	Associate Investigator(s): Timothy O'Rourke, M.D. Terry Jenkins, M.D. Howard A. Burris, III, M.D. David A. Rinaldi, M.D. Ralph F. Heaven, M.D.
Key Words: Doxorubicin, Vincristine, Cyclophosphamide, Prednisone, Non- Hodgkin's, refractory, relapsed	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 0  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To study the safety and tolerability of SDZ PSC 833 in combination with doxorubicin, vincristine, cyclophosphamide and prednisone (P-DVCP). To evaluate the efficacy (i.e., complete response rate and duration disease free and overall survival) of P-DVCP in refractory or relapsed intermediate or high grade non-Hodgkin's lymphoma (NHL). To determine the MTD of P-DVCP. To study the correlation of *mdrl* gene expression in tumor specimens with clinical response to P-DVCP.

Technical Approach: Study population, treatment assignment, medication, visit schedule/evaluation and other specifics are outlined in protocol.

Progress: No patients have been eligible at BAMC. Six patients at other sites have been treated, with significant neutropenia and fever seen in four. The protocol is to be amended to allow a reduction in the dose of doxorubicin.

# Detail Summary Sheet

Date: 1 Dec 94      Protocol Number: C-94-69      Status: Ongoing

Title: Phase II Trial of Taxotere in Patients with Hormone Refractory Prostate Cancer to Determine Clinical Benefit

Start date: 20 Sep 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: UTHSCSA, CTSC & Brooke Army Medical Center, Texas
Department/Service: Medicine/Hem-Onc	Associate Investigator(s): Timothy O'Rourke, M.D. Terry Jenkins, M.D. Patrick Cobb, M.D. David A. Rinaldi, M.D. Ralph F. Heaven, M.D.
Key Words: Taxotere, HRPC, PSA, Karnofsky performance status, pain palliation	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 0  
Periodic review date: \_\_\_\_\_ Review results: Continue

Objective(s): To assess the antitumor effect of taxotere in patients with hormone refractory prostate cancer (HRPC) as measured by decline in serum prostate specific antigen (PSA). To assess the clinical benefit of intravenous taxotere in patients with HRPC as measured by time to disease progression, Karnofsky performance status, and pain palliation. To determine the objective response rate of intravenous taxotere in those patients with HRPC and measurable disease. To evaluate the qualitative and quantitative toxicities of intravenous taxotere in patients with HRPC.

Technical Approach: Patient eligibility, treatment plan, drug administration, and detailed specific are outlined in protocol.

Progress: Accrual goes slowly. No unexpected toxicities to date. Some hints of clinical benefit observed.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-70                      Status: Terminated

Title: Efficacy of Furosemide Versus Hydrochlorothiazide Induced Natriuresis and Diuresis in Chronic Renal Insufficiency Patients

Start date: 22 Mar 94	Estimated completion date:
Principal Investigator: William Gutheim, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Nephrology Svc	Associate Investigator(s): Domenic Sica, M.D. Alicia Loube, RD
Key Words: Furosemide, Hydrochlorothiazide, Natriuresis, Diuresis,	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): Furosemide and hydrochlorothiazide are both able to induce clinically significant diuresis and natriuresis in patients with moderate chronic renal insufficiency if doses are sufficiently increased.

Technical Approach: Chronic renal insufficiency patients often require diuretic as adjunctive therapy for hypertension and congestive heart failure. Management of hypertension and exacerbations of congestive heart failure can be assisted by inducing both diuresis and natriuresis. Demonstration of the efficacy of both furosemide and hydrochlorothiazide in chronic renal insufficiency patients can offer clinicians as alternate choice in the treatment of patients with chronic renal insufficiency.

Progress: All physicians participating in this protocol have PCSd. No one currently in the Nephrology Service is familiar with this study.



# Detail Summary Sheet

Date: 1 Dec 94 Protocol Number: C-94-72 Status: Ongoing

Title: Comparison of Cost Effectiveness of Visual Blood Glucose Monitoring and One Touch in An Outpatient Diabetic Clinic: Effects on Glycosylated Hemoglobin .

Start date: 25 Mar 94	Estimated completion date:
Principal Investigator: Rosemary Chacko, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gen Med Svc	Associate Investigator(s): Richard Marple Linore Bouska
Key Words: Glycosylated Hemoglobin, Glucose V	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:
Number of subjects enrolled during reporting period: 0	
Total number of subjects enrolled to date: 0	
Periodic review date: Review results:	

Objective(s): 1. Compare patient interpretation of the Glucose V visual blood glucose test with the One Touch mechanized display. 2. To follow patients placed on the Glucose V visual blood glucose test to see if the diabetic control based on glycosylated hemoglobin has worsened. 3. To delineate subgroups of patients that may utilize Glucose V visual blood glucose tests at significant cost savings compared to the One Touch, without harm to overall diabetic control.

Technical Approach: Most patients will show significant worsening of glycosylated hemoglobin with Glucose V when compared with One Touch.

Progress: Due to the recent delivery and maternal leave of MAJ Chacko and the pending delivery and maternal leave of CPT Bouska, this project has not been started. We anticipate starting this fall 94.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-79                      Status: Ongoing

Title: Influence of Hyperimmune Serum Products on Panel Reactive Antibody Determinations

Start date: 7 Apr 94	Estimated completion date:
Principal Investigator: J. William Kelly, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Infectious Disease	Associate Investigator(s): William W. Ward, BSC Ted Freeman, M.D. Elizabeth M. Menchaca, DAF Linda K. Porter, DAC
Key Words: Hyperimmune, Klebsiella, Pseudomonas, nosocomial	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 12  
 Total number of subjects enrolled to date: 12  
 Periodic review date: Review results:

Objective(s): To study the effect of administration of a hyperimmune serum against Klebsiella and Pseudomonas on the panel reactive antibody assay.

Technical Approach: Ten pre- and post-infusion serum specimens from the Federal Hyperimmune Immunotherapy Trial (FHIT) will be chosen for PRA determinations. The FHIT is an ongoing randomized placebo-controlled trial to determine the effectiveness of a hyperimmune serum obtained from volunteers who had been immunized with a combined Klebsiella/Pseudomonas capsular vaccine in preventing nosocomial infections.

Progress: Serum has been collected and awaiting to be processed.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-82                      Status: Ongoing

Title: A Randomized, Double-Blind Study Comparing Megace Plus Hydroxyurea to Megace Plus Placebo in Patients with Advanced Cancer

Start date: 20 Dec 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Timothy O'Rourke, M.D. Terry Jenkins, M.D. Patrick Cobb, M.D. David A. Rinaldi, M.D. Ralph F. Heaven, M.D.
Key Words: Megace, Hydroxyurea, placebo	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 3  
Total number of subjects enrolled to date: 3  
Periodic review date: \_\_\_\_\_ Review results: Continue

Objective(s): The primary endpoint for this study is to determine whether low dose of hydroxyurea prolongs survival in patients with advanced cancer. To determine the toxicity of low dose hydroxyurea plus megace in patients with advanced cancer. To determine the impact of hydroxyurea on quality of life of patients with advanced cancer.

Technical Approach: Background/rationale, drug information, patient eligibility, treatment plan and other specifics are outlined in protocol.

Progress: Accrual goes well to this study. The double-blinded nature of the protocol prevents any preliminary analysis. No unexpected toxicities to date.

# Detail Summary Sheet

Date: 1 Dec 94      Protocol Number: C-94-83      Status: Completed

Title: Phase II Trial of RP56976 in Patients with Non-Small Cell Lung Cancer Previously-Untreated with Cytotoxic Chemotherapy

Start date: 20 Apr 92	Estimated completion date:
Principal Investigator: Howard A. Burris, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Timothy O'Rourke, M.D. Terry Jenkins, M.D. Patrick Cobb, M.D. David A. Rinaldi, M.D. Ralph F. Heaven, M.D.
Key Words: Cytotoxic, Non small cell lung cancer (NSCLC)	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 34

Total number of subjects enrolled to date: 34

Periodic review date: Review results:

Objective(s): To estimate the major objective response rate and duration of response of RP 56976 in patients with NSCLC previously untreated with cytotoxic chemotherapy. To determine the qualitative and quantitative toxicity and reversibility of toxicity of RP 56976 administered as an intravenous infusion over one hour every 21 days.

Technical Approach: Patient definition, plan of the study, efficacy and safety measurements, data analysis, and other specifics are outlined in protocol.

Progress: Accrual completed with a total of 34 patients enrolled. An objective response rate of 31% was observed, with a median survival of 7.4 months. Results were presented at the ASCO meeting in 1993 and the International Lung Cancer Conference in 1994. A manuscript is prepared and is being reviewed by the sponsor.

# Detail Summary Sheet

Date: 1 Dec 94      Protocol Number: C-94-84      Status: Ongoing

Title: A-Phase II Study to Determine the Anti-Tumor Effect of Intravenous Ilmofofosine Administered as a 120-Hour Infusion Every 21 Days to Patients with Non-Small Cell Lung Cancer

Start date: 20 Dec 93	Estimated completion date:
Principal Investigator: Howard Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Timothy O'Rourke, M.D. Terry Jenkins, M.D. Patrick Cobb, M.D. David A. Rinaldi, M.D. Ralph F. Heaven, M.D.
Key Words: Ilmofofosine, Non-Small Cell Lung Cancer, intravenous, toxicity, Sulfoxide	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Review results: Continue

Objective(s): To assess the antitumor effect of five day (120-hr) infusion of intravenous ilmofofosine in patients with non small cell lung cancer; to assess the toxicity of ilmofofosine; and to evaluate the serum concentration-time profile of ilmofofosine and the sulfoxide metabolite at steady state.

Technical Approach: Detailed study plan, methods and other details are outlined in protocol.

Progress: Accrual continues to a total of 20 patients. No antitumor activity has been observed to date. Sporadic, ill-defined pulmonary toxicity has been observed in several patients.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-85                      Status: Ongoing

Title: A Phase I Study of Docetaxel (RP56976) and 5-Fluorouracil Combination Chemotherapy in Patients with Advanced Solid Tumor

Start date: 20 Dec 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Timothy O'Rourke, M.D. Terry Jenkins, M.D. Patrick Cobb, M.D. David A. Rinaldi, M.D. Ralph F. Heaven, M.D.
Key Words: Docetaxel, 5-Fluorouracil, advanced solid tumors, first-line chemotherapy	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:
Number of subjects enrolled during reporting period: <u>1</u>	
Total number of subjects enrolled to date: <u>1</u>	
Periodic review date: _____ Review results: <u>Continue</u>	

Objective(s): Phase I: To determine the maximum tolerated doses (MTD) of docetaxel and 5-FU in combination, when given to patients with advanced solid tumors. Phase II: To determine the efficacy of docetaxel and 5-FU in combination as first line chemotherapy in advanced breast cancer, with evaluation of objective response rate, duration of response, and time to disease progression.

Technical Approach: Entry criteria, plan of the study, data analysis and other specifics outlined in protocol.

Progress: Sporadic toxicities, not felt to be drug related, have necessitated adding additional dose levels and patients to this trial. Accrual goes well and good antitumor activity has been observed with this combination.

# Detail Summary Sheet

Date: 1 Dec 94      Protocol Number: C-94-86      Status: Ongoing

Title: Serum Collection Study on Patients with Active Colon or Breast Cancer

Start date: 20 Sep 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Timothy O'Rourke, M.D. Terry Jenkins, M.D. Patrick Cobb, M.D. David A. Rinaldi, M.D. Ralph F. Heaven, M.D.
Key Words: monoclonal antibodies, nuclear matrix proteins (NMP), sera, immunoassays	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To evaluate monoclonal antibodies for cancer specific nuclear matrix proteins (NMP) utilizing well documented sera from patients with breast or colon cancer. Identify immunoassays capable of detecting breast or colon cancer in human serum.

Technical Approach: Eligibility criteria, study design, and detailed specifics are outlined in protocol.

Progress: This trial has not been initiated as the statistical parameters to be utilized have not been properly defined.

# Detail Summary Sheet

Date: 1 Dec 94 Protocol Number: C-94-87 Status: Completed

Title: A Double-Blind, Randomized, Parallel, Sotalol-Controlled, Dose Confirmation Study to Investigate the Safety and Electrophysiologic Effects of MK-499 in Patients with Sustained Ventricular Tachyarrhythmias

Start date: 24 Jan 94	Estimated completion date:
Principal Investigator: James K. Gilman, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s):
Key Words: Sotalol-controlled, electrophysiologic, Ventricular Tachyarrhythmias (VT)	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Review results:

Objective(s): 1. To determine the safety and tolerability of two oral doses of MK-499 in the patients with sustained VT. 2. To determine an oral dose or a dose range of MK-499 which suppresses induction of sustained VT during EP testing in >30% of patients with sustained ventricular tachyarrhythmias. 3. To compare the safety, efficacy and EP effects of MK-499 to sotalol.

Technical Approach: Patient definition, study design, concurrent treatment, data analysis and detailed specifics are outlined in protocol.

Progress: Closed by the drug company.



# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-88                      Status: Ongoing

Title: A Double-Blinded, Randomized Trial Comparing Zidovudine (ACV) vs, ZDV + Didanosine (ddI) vs, ZDV + ddI + Nevirapine in Asymptomatic Patients on ADV Monotherapy Who Develop a Mutation at Codon 215 of HIV Reverse Transcriptase in Serum/Plasma Viral RNA

Start date: 14 Apr 94	Estimated completion date:
Principal Investigator: M. Patricia Joyce, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Infectious Disease	Associate Investigator(s):
Key Words: Zidovudine (ACV), Didanosine, mutation, transcriptase, serum/plasma, viral RNA, codon 215	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2  
 Total number of subjects enrolled to date: 2  
 Periodic review date: Review results:

Objective(s): Primary: 1. To validate that alteration of codon 215 of reverse transcriptase in plasma virus precedes the increase in viral burden as measured in the peripheral blood and decline in CD4 count which have been observed in association with clinical failure on zidovudine. 2. To determine whether alternative regimens of antiretroviral agents alter the course of viral burden as measured in the peripheral blood and CD4 changes when initiated on the basis of plasma RNA PCR results.

Technical Approach: Patient selection/enrollment, study treatment, clinical/laboratory evaluations and other specifics are outlined in protocol.

Progress: This double blinded study is to continue next 4-5 years. The two patients are tolerating fine, no side effects.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-89                      Status: Ongoing

Title: A Randomized, Controlled, Multicenter Trial of Filgrastim (Recombinant-methionyl Human Granulocyte Colony Stimulating Factor) for the Prevention of Grade 4 Neutropenia in Patients with HIV Infection

Start date: 5 Apr 94	Estimated completion date:
Principal Investigator: M. Patricia Joyce, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Infectious Disease Svc	Associate Investigator(s):
Key Words: Filgrastim, Human Granulocyte Colony Stimulating Factor, Grade 4 Neutropenia	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 1  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine the efficacy of Filgrastim (r-metHuG-CSF) for the prevention of Grade 4 neutropenia (ANC<500/mm<sup>3</sup>) in patients with HIV infection.

Secondary: To compare the incidence of culture confirmed bacterial infections and fungal infections, use of IV antibacterial and antifungal agents, use of myelosuppressive drugs, and hospitalizations in patients randomized to Filgrastim treatment versus patients randomized to observation. To compare all adverse events and the incidence of death in patients randomized to Filgrastim treatment versus patients randomized to observation.

Technical Approach: Background and rationale, experimental plan, patient eligibility/enrollment, study drugs, treatment procedures and further details are outlined in protocol.

Progress: Patient is about to complete a 6-month study period without complication. Drug company wants him to go on open label drug but still working on the funding of this.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-90                      Status: Ongoing

Title: Cognitions, Depression, Quality of Life, and Will-to-Live in Lung Cancer Patients

Start date: 11 Apr 94	Estimated completion date:
Principal Investigator: Brenda J. Moretta, Doctoral Candidate	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology Svc	Associate Investigator(s): Jean M. Johnson, Ph.D. RN Timothy O'Rourke, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 29 BAMC; 68 total  
 Total number of subjects enrolled to date: 29  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): Attempt to study the relationships between cognitive appraisals, depression, quality of life, and will-to-live in lung cancer patients.

Technical Approach: Characteristics of subjects, subject recruitment, measures, confidentiality of data, etc, covered in protocol.

Progress: Data collection has been completed. Data analysis is nearly complete and my dissertation should be completed in January.

# Detail Summary Sheet

Date: 1 Dec 94 Protocol Number: C-94-91 Status: Completed

Title: A Single Blinded, Randomized, Placebo Controlled Trial Comparing Meat Tenderizer, Vinegar and Bicarbonate in the Symptomatic Relief of Acute Fire Ant Stings...

Start date: 29 Apr 94	Estimated completion date:
Principal Investigator: David W. Harden, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine	Associate Investigator(s): Beth Honl, M.D.
Key Words: meat tenderizer, vinegar, bicarbonate, placebo	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 7  
Total number of subjects enrolled to date: 7

Periodic review date: Review results:

Objective(s): To compare the efficacy of meat tenderizer versus vinegar versus bicarbonate versus a placebo in the symptomatic relief of acute fire ant stings.

Technical Approach: Power analysis statement: To estimate the efficacy of meat tenderizer, vinegar and bicarbonate, detecting a difference of 50% between the treated stings versus the control with a standard deviation of one-half of the test difference. Using the statistical method of analysis of variance, we will need 5 volunteers per group for a 95% level of confidence with a power of 0.8 and alpha of 0.05.  
The fire ants will be collected from a local mound and be promptly transported to the Dermatology Clinic to maintain adequate vigor. Approximately 6 volunteers will be selected among dermatology residents and staff who lack a prior history of an adverse reaction to fire ants, bees, wasps, yellow jackets, and/or hornets. Further details in protocol.

Progress: No significant difference. Paper forthcoming.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-95                      Status: Ongoing

Title: The Effect of Acemannan on UVB-Induced Erythema

Start date: 9 May 1994	Estimated completion date:
Principal Investigator: Vincent L. Angeloni, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Dermatology Service	Associate Investigator(s): Dirk Elston, M.D. Richard Vinson, M.D.
Key Words: Acemannan UVB-Induced Erythema, banal hydrogel, double-blinded	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Review results:

Objective(s): To evaluate whether topical application of acemannan has any beneficial effect on the erythema induced by ultraviolet B light (i.e. sunburn) when applied before and after light exposure. The study will utilize healthy volunteers who will be exposed to a measured dose of ultraviolet B (UVB) to small areas of non-sun exposed skin which have been treated with acemannan gel before exposure and after exposure. The resulting erythema will then be evaluated to discern any effect induced by the application of the acemannan.

Technical Approach: The hypothesis to be tested in this experiment is that acemannan applied to the skin will either attenuate the erythema induced by UVB exposure or enhance its resolution. Thus, we will evaluate the UVB responses of untreated skin, skin treated with a banal hydrogel (K-Y jelly) and skin treated with acemannan gel. Erythema responses will be quantified visually in a double-blinded fashion.

Progress: Currently awaiting approval of a CRDA grant which will allow payment of volunteers for their participation. We anticipate that this will enable us to rapidly enroll volunteers and complete the study within 2-3 months.

# Detail Summary Sheet

Date: 1 Dec 94 Protocol Number: C-94-99 Status: Ongoing

Title: A Phase I Study to Determine the Maximum Tolerated Dose of Topotecan Following Oral Administration Over 21 Days in Patients with Malignant Solid Tumors

Start date: 28 Feb 94	Estimated completion date:
Principal Investigator: Howard A. Burris, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Frank W. Cobb, M.D. Gail Eckhardt, M.D. Ralph F. Heaven, M.D. Stephen Kalter, M.D. Timothy J. O'Rourke, M.D.
Key Words: Topotecan, dose levels, antitumor activity	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Review results:

Objective(s): To determine the qualitative and quantitative toxicity of Topotecan when given by oral administration over 21 out of every 28 days and to establish an MTD using this schedule. To determine pharmacokinetics and steady state levels achieved after prolonged oral dosing over a range of dose levels and to document any antitumor activity observed using this schedule.

Technical Approach: Study population, conduct of the study, study medication, etc, outlined in protocol.

Progress: Accrual has recently been initiated to this study. No unexpected toxicities observed to date.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-103                      Status: Ongoing

Title: Safety and Immunogenicity of a Cell Cultured Vaccinia Virus Vaccine (TSI-GSD-241) Administered by the Intradermal and Intramuscular Routes Compared with Wyeth Dryvax Administered by Scarification

Start date: 16 June 1994	Estimated completion date:
Principal Investigator: Shannon Harrison, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Infectious Disease	Associate Investigator(s): Curtis Yeager, MAJ, MS Michael S. Wright, CPT, MS
Key Words: Dryvax, Scarification, intradermally, intramuscularly	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To compare the safety and immunogenic potency of a cell cultured vaccinia virus vaccine candidate administered intradermally and intramuscularly with the Wyeth Dryvax vaccine administered by scarification. This open label study seeks to enroll up to 114 volunteers, who will be divided into 3 groups based upon randomization. Volunteers will receive the vaccines at the clinical unit of BAMC or at a designated treatment area at the Academy of Health Sciences.

Technical Approach: Selection of volunteers, study population, screening, criteria for acceptance, etc, covered in protocol.

Progress: Approximately 100 subjects were recruited from 3 different AHS classes. Subjects received 1) Wyeth Dryvax by scarification, or new cell-cultured vaccinia vaccine by 2) intradermal or 3) intramuscular. Subjects were monitored and tested for overall health and virus titer for 28 days. Results are pending data analysis.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-105                      Status: Ongoing

Title: The Use of Albuterol in the Premedication of Patients with Chronic Obstructive Pulmonary Disease Undergoing Routine Flexible Fiberoptic Bronchoscopy

Start date: 21 Jun 94	Estimated completion date:
Principal Investigator: John Atkins, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Pulmonary Disease	Associate Investigator(s): Mark D. Peacock, M.D. Herman M. Blanton, M.D.
Key Words: Albuterol, flexible fiberoptic bronchoscopy (FFB), nebulized	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 7  
 Total number of subjects enrolled to date: 7  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To evaluate the effect of premedication with nebulized albuterol upon post-procedural complication rates in patients with chronic obstructive pulmonary disease (COPD) undergoing routine flexible fiberoptic bronchoscopy (FFB).

Technical Approach: Adult male and female patients with a clinical history consistent with COPD and with spirometric evidence of an obstructive ventilatory defect, that are to undergo a medically indicated bronchoscopic procedure. The criterion for a significant obstructive ventilatory defect is a difference of at least 9% between the predicted FEV<sub>1</sub>/FVC ratio and the actual FEV<sub>1</sub>/FVC ratio in women and a similar difference of 8% in men. All subjects will not use any inhaled bronchodilators four hours prior to the procedure.

Progress: Seven patients have been enrolled to date; no complications have been noted in either group.



# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-106                      Status: Ongoing

Title: A Phase II Trial of Iriotecan Hydrochloride (CPT-11) for Patients with 5-FU-Refractory Colorectal Cancer

Start date: 11 Jun 94	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Timothy O. Rourke, M.D. Terry Jenkins, M.D. Patrick Cobb, M.D. David A. Rinaldi, M.D. Ralph F. Heaven, M.D.
Key Words: Irinotecan Hydrochloride, 5-FU, active metabolite	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 5  
Total number of subjects enrolled to date: 5  
Periodic review date: \_\_\_\_\_ Review results: Continue

Objective(s): To assess the antitumor activity of irinotecan (CPT-11) when administered once a week for 4 consecutive weeks, followed by a 2 week rest, in patients with metastatic colorectal cancer that has progressed within 6 months of one prior 5-fluorouracil (5-FU)-based chemotherapy. To evaluate the qualitative and quantitative toxicities of irinotecan on the schedule in this population. To ascertain the pharmacokinetics of irinotecan and the active metabolite (SN-38) in this population.

Technical approach: Staging criteria, eligibility, exclusion, treatment plan, dosage modifications, etc., details covered in protocol.

Progress: Rapid accrual has been accomplished. 19 patients were entered in San Antonio with a total of 200 enrolled nationally. Results are not yet available regarding antitumor efficacy.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-109                      Status: Ongoing

Title: Gastric Hyposecretion in Patients with Walter Reed Stage 6 HIV-1 Infection--

Start date: 23 Jun 94	Estimated completion date: 12 Feb 94
Principal Investigator: Charles A. Farrington, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology Service	Associate Investigator(s): Shailesh C. Kadakia, M.D. Patricia Joyce, M.D. Richard Schaeffer, M.D.
Key Words: cutaneous anergy, gastric acid secretion, WR-6	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2  
Total number of subjects enrolled to date: 2  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To investigate a population of WR6 AIDS patients prospectively for incidence of AIDS associated gastric secretory failure, and survey them for incidence of chronic diarrhea so as to determine if the secretory failure is associated with an increased frequency of chronic diarrhea.

Technical Approach: Twenty-six subjects with WR Stage 6 AIDS will be required. Ten healthy age-matched control volunteers will serve for comparison of gastric acid secretion between the two groups. Selection of patients for the study will be based on the Walter Reed Staging System for HIV-1 infection. All patients will have clinical AIDS, defined as WR-6. This is defined as being positive for HIV, having a T4 cell count < 400, partial or complete cutaneous anergy, and the presence of opportunistic infections other than thrush. Further details outlined in protocol.

Progress: Two HIV-6 patients enrolled to date. Neither patient had a complaint of chronic diarrhea and neither patient was found to have gastric acid hyposecretion.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-110                      Status: Ongoing

Title: A Prospective Randomized Double-Blind Study Comparison of Flexible Fiberoptic-Bronchoscopy with and without the Use of Preprocedure Sedation

Start date: 28 Jun 94	Estimated completion date:
Principal Investigator: James P. Bradley, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Pulmonary Disease Service	Associate Investigator(s): Mark D. Peacock, M.D.
Key Words: Flexible Fiberoptic Bronchoscopy, respiratory depression, cardiac arrhythmias	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): Over 50% of life threatening complications from flexible fiberoptic bronchoscopy are from the premedications given, and are primarily due to respiratory depression and cardiac arrhythmias. The majority of procedures are performed on an outpatient basis; therefore, cost containment from medications given, observation required, as well as the need for hospitalization are important. A prospective study is needed to compare outcomes with and without use of premedication during flexible fiberoptic bronchoscopy for tolerance and whether a significant time and cost savings can be realized.

Technical Approach: Subjects - Male and female patients older than 18 years of age, who require routine bronchoscopy, will be asked to volunteer to participate in this study. After informed consent is obtained, patients will be randomized to two groups. The study group will be premedicated with atropine, 0.6mg, and versed, 0.07 mk/kg, intramuscularly. The control group will be given a placebo consisting of normal saline IM in equal volumes given the first group. Both groups will get the injection 30 minutes prior to the start of the procedure. The patient, the technician, and the bronchoscopist will be blinded to the premedication given.

Progress: Enrollment to begin September 1994.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-112                      Status: Ongoing

Title: Phase II Study: Treatment of Lymphoma with High-Dose Chemotherapy Consisting of BCNU, Cytosan, and VP-16 with Autologous Stem Cell Support and Cyclosporine-A Immunomodulation

Start date: 6 Jul 94	Estimated completion date:
Principal Investigator: Svetislava J. Vukelja, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hem-Onc	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 13  
Total number of subjects enrolled to date: 13  
Periodic review date: Review results:

Objective(s): To assess the efficacy of high dose BCNU, VP-17, and cyclophosphamide with autologous hematopoietic stem cell transplantation in the treatment of selected patients with poor-prognosis Hodgkin's disease or high- or intermediate-grade non-Hodgkin's lymphoma.

Technical Approach: Eligibility criteria, treatment plan, drug information and detailed specifics are given in protocol.

Progress: We will also add cyclosporin to the regimen to improve results.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-123                      Status: Ongoing

Title: Evaluation of Cardiac Output Determination by the MedGraphics Gas Analysis System Using Invasive Thermodilution and Standard Metabolic Cart Comparisons-

Start date: 19 Jul 94	Estimated completion date:
Principal Investigator: Ricky D. Latham, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s): Bernard J. Rubal, Ph.D. William T. Wright, M.D. Suzanne M. Fortney, Ph.D.
Key Words: Invasive thermodilution, MedGraphics Gas Analysis, MedGraphics metabolic cart	
Cumulative MEDCASE cost: .00	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 3  
Total number of subjects enrolled to date: 3  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1. Compare cardiac output determinations during exercise using a noninvasive CO2 rebreathing device to the standard thermodilution catheter.  
2. Compare oxygen consumption determinations using the MedGraphics Gas Analysis system vs the standard MedGraphics metabolic cart.

Technical Approach: Subjects eligible will be those scheduled to undergo routine elective right and left heart catheterization. Inclusion/exclusion specifics, data analysis, risks and other details outlined in protocol.

Progress: Software problems with NASA equipment have delayed further patient entry.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-125                      Status: Completed

Title: Gemcitabine in Patients with Refractory Pancreas Cancer

Start date:	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine-Hem/Onc	Associate Investigator(s): Oncology staff and fellows
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 3  
 Total number of subjects enrolled to date: 5  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To provide for the treatment with gemcitabine and collect the best overall tumor response of patients with pancreatic cancer who have progressed or shown to be refractory to 5-Fluorouracil (5-FU) therapy as administered on B9E-MC-JHAY: Gemcitabine versus 5-Fluorouracil in a Randomized Trial as first-Line Palliative Therapy in Patients with Carcinoma of the Pancreas.

Technical Approach: Patient eligibility criteria, dosage/administration, tumor response criteria, data analysis and further details are outlined in protocol.

Progress: Accrual has completed for this trial. Gemcitabine was extremely well tolerated and provided substantial clinical benefit to a number of patients. Final results are pending. Of note, two BAMC patients are among the long term survivors from this trial.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-126                      Status: Ongoing

Title: A Pilot Study of Docetaxel (RP 56976) in Patients with Paclitaxel-Resistant Advanced Breast Cancer

Start date:	Estimated completion date:
Principal Investigator: Howard Burris, III, M.D.	Facility: CTRC Brooke Army Medical Center, Texas
Department/Service: Medicine/Hem-Onc	Associate Investigator(s): Timothy O'Rourke, M.D. Terry Jenkins, M.D. Patrick Cobb, M.D. David A. Rinaldi, M.D. Ralph F. Heaven, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 1  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine the objective response rate, duration of response, and toxicity of docetaxel in patients with Stage IV paclitaxel-resistant breast cancer. To examine changes in quality of life over time in patients receiving docetaxel and to correlate scores with response and with toxicity frequencies.

Technical approach: Study objectives, patient identification, plan of the study and further details are covered in protocol.

Progress: Accrual has been initiated with 3 patients enrolled to date including 1 at BAMC. Too early to assess response. Accrual will continue.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-127                      Status: Ongoing

Title: A Phase I Study of SCH 52365 in Adult Patients with Advanced Cancer Stratified by Extent of Prior Therapy

Start date:	Estimated completion date:
Principal Investigator: Howard Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hem-Onc	Associate Investigator(s): Timothy O'Rourke, M.D. Terry Jenkins, M.D. Patrick Cobb, M.D. David A. Rinaldi, M.D. Ralph F. Heaven, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 3  
 Total number of subjects enrolled to date: 3  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To characterize the safety profile and determine the DLT and MTD of SCH 52365 when administered orally, once a day for 5 days in adult patients with advanced cancer who have no bone marrow involvement with tumor and who have been heavily pretreated with therapy defined as poor risk. To characterize the safety profile and determine the DLT and MTD of SCH 52365 when administered orally, once a day for 5 days in adult patients with advanced cancer who have no bone marrow involvement with tumor and who have been less heavily pretreated with therapy defined as good risk. To characterize the single- and multiple-dose pharmacokinetics of SCH 52365 in both these patient populations.

Technical Approach: Study design, patient population, conduct of study, treatment and further details outlined in protocol.

Progress: Accrual is proceeding rapidly on this phase I trial. Minimal toxicities have been observed to date. A partial response has been observed in a patient from BAMC with metastatic melanoma. Dose escalation continues.



# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-129                      Status: Ongoing

Title: Evaluation of the Clinical and Cost Effectiveness of Therapy with Clarithromycin Plus Omeprazole Compared to Omeprazole or Ranitidine for the Treatment of Patients with Duodenal Ulcer and Helicobacter pylori Infection

Start date: 9 Aug 94	Estimated completion date:
Principal Investigator: Shailesh C. Kadakia, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastro Svc	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): The primary objectives of this study are to assess the clinical outcomes and medical costs of treatment with clarithromycin plus omeprazole versus omeprazole alone or ranitidine alone in the treatment of patients with a duodenal ulcer who have a confirmed H. pylori infection. The clinical response of the patient will be used as the primary measurement of efficacy. All utilization of medical care related to duodenal ulcer, both direct and indirect, will be collected for the entire study period.

Technical Approach: Study design/description, patient selection criteria, exclusion criteria, study materials, and further details are outlined in protocol.

Progress: This is a new study. There is no reportable data.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-130                      Status: Ongoing

Title: Spanish Translation and Validation of a Quality of Life Questionnaire

Start date: 11 Aug 94	Estimated completion date:
Principal Investigator: Timothy O'Rourke, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hem-Onc Svc	Associate Investigator(s): Ian M. Thompson, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): Cancer and its treatment can affect any one of the following areas of life: physical functioning; emotional functioning; general symptoms; symptoms commonly associated with treatment for breast and prostate cancer; general health and quality of life. It is very important to have a patient's view of how he or she has been feeling during the treatment. This information can help the physician and patient make decisions about the best care for the patient.

Technical Approach: Study procedures and further details outlined in protocol.

Progress: This is a new study. There is no reportable data.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-131                      Status: Ongoing

Title: Attitudes of Physicians Regarding Blood Transfusion Therapy and Blood Donation --

Start date:	Estimated completion date:
Principal Investigator: Leonard E. Deal, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Pulmonary Disease	Associate Investigator(s): Mark D. Peacock, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To identify physician attitudes towards the replenishment of blood supplies and to evaluate them within the context of the physicians' utilization of these stores.

Technical: A questionnaire will be used in an attempt to survey every physician assigned to BAMC. Initial effort will be contacting every departmental chief and ask permission to discuss the purpose of this survey with their physicians during a routine, scheduled meeting for that department. The results of the surveys will be analyzed with respect to level of training, medical specialty, and transfusion ordering habits. Statistical comparisons of transfusion rates will be compared by the Chi-square test of independence (for donat vs. do not donate) and the rank sum test.

Progress: This is a new study. There is no reportable data.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-135                      Status: Ongoing

Title: A Phase II Multicenter Clinical Trial to Evaluate the Safety, Efficacy and Pharmacokinetics of MP 840 Given Every Four Weeks (Q4W) in Patients with Advanced Refractory Colorectal Cancer

Start date: 20 Jun 94	Estimated completion date:
Principal Investigator: Patrick Cobb, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Oncology Staff and Fellows
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2  
 Total number of subjects enrolled to date: 2  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine the objective response rate in patient with advanced refractory colorectal cancer treated with DMP 840 once every 4 weeks. To characterize the safety profile of DMP 840 in this patient population. To evaluate secondary effectiveness parameters such as duration of objective response, time to disease progression, survival, and changes in performance status and weight.

Technical Approach: The enrollment period for this study is expected to be 12 months. Each patient will be treated with a six-hour central venous infusion of DMP 840 on a once every 4 weeks schedule. The starting dose will be 60 mg/m<sup>2</sup> of DMP 840 for good risk patients and 50 mg/m<sup>2</sup> for poor risk patients. Blood samples of DMP 840 pharmacokinetic analysis will be obtained during the first course of treatment. Objective response will be evaluated by the measurement of indicator lesions once every two courses. Further details outlined in protocol.

Progress: Accrual has proceeded rapidly with this trial. The initial 20 patients have been accrued and we are awaiting documentation of objective responses before proceeding to the second phase of accrual.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-136                      Status: Ongoing

Title: A Phase II Multicenter Clinical Trial to Evaluate the Safety, Efficacy and Pharmacokinetics of DMP 840 Given Every Four Weeks (Q4W) in Patients with Advanced Refractory Breast Cancer

Start date: 20 Jun 94	Estimated completion date:
Principal Investigator: Patrick Cobb, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Review results:

Objective(s): To determine the objective response rate in patients with advanced refractory breast cancer treated with DMP 840 once every 4 weeks. To characterize the safety profile of DMP 840 in this patient population. To evaluate secondary effectiveness parameters such as duration of objective response, time to disease progression, survival and changes in performance status and weight.

Technical Approach: This is an open-label, non-randomized, multiple dose, multicenter Phase II trial.

Progress: This trial has recently been initiated and no patients have been accrued to date. A total of 20 patients will be enrolled from four centers at which time patients will be evaluated to determine whether objective responses have been obtained.

# Detail Summary Sheet

Date: 1 Dec 94      Protocol Number: C-94-137      Status: Ongoing

Title: The Coronary Stent in the Treatment of Cases Which Have Failed Standard Nonsurgical Techniques and Cases Predisposed to a Poor Outcome

Start date: 24 Aug 94	Estimated completion date:
Principal Investigator: Douglas G. Ebersole, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To evaluate the safety and efficacy of the PALMAZ-SCHATZ™ coronary stent in the treatment of cases that have failed standard nonsurgical techniques such as suboptimal PTCA or threatened abrupt closure or are cases where standard nonsurgical or surgical techniques are at high risk to have an outcome complicated by death or myocardial infarction. Initial success will be defined as successful deployment of the stent, achieving patency of the target artery with a residual stenosis < 50% and no major complication (death, MI, bypass of the target lesion).

Technical approach: Details outlined in protocol.

Progress: This is a new study. There is no reportable data.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-142                      Status: Completed

Title: A Phase I Dose Finding Study of Microencapsulated Sandostatin LAR Given IM to Patients with Advanced Cancer

Start date: 16 May 94	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology-Oncology	Associate Investigator(s): Timothy O'Rourke, M.D. Terry Jenkins, M.D. Patrick Cobb, M.D. David A. Rinaldi, M.D. Ralph F. Heaven, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:
Number of subjects enrolled during reporting period: 0	
Total number of subjects enrolled to date: 0	
Periodic review date:                      Review results:	

Objective(s): To define the safety and tolerability of 90 mg Sandostatin LAR in patients with advanced cancer, given monthly, biweekly and weekly. To study the pharmacokinetics of 90 mg Sandostatin LAR when given in the above noted cohorts. Secondary: To determine if tumor shrinkage is observed in advanced cancer patients receiving 90 mg Sandostatin LAR.

Technical Approach: The investigational plan, study population, treatment assignment, medication, visit schedule/evaluations and specifics are outlined in protocol.

Progress: This trial is closed to accrual. The initial cohort of patients were enrolled rapidly with excellent results. The second phase of accrual could not be initiated because of supply problems from the manufacturer.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-143                      Status: Ongoing

Title: Thrombus Formation During Coronary Angioplasty in Acute Ischemic Syndromes: Influence of Contrast Media

Start date: 22 Sep 94	Estimated completion date:
Principal Investigator: Miguel A. Campos, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s): Douglas Ebersole, M.D. William Wright, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine if contrast media (ionic vs nonionic) impacts on the incidence of thrombus formation during coronary angioplasty in patients with unstable angina pectoris.

Technical Approach: The choice of contrast agent may affect the incidence of thrombus formation, acute ischemic complications and costs. This study will help define if ionic or nonionic contrast media should be utilized in patients with unstable ischemic syndromes undergoing coronary angioplasty. Further details outlined in protocol.

Progress: This is a new study. There is no reportable data.



# Detail Summary Sheet

Date: 1 Dec 94      Protocol Number: C-94-146      Status: Ongoing

Title: A Phase III Trial of Crismatol Mesylate vs BCNU in the Consolidative Treatment of Glioblastoma Multiforme

Start date: 03 Mar 94	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Audie Murphy, CTSC, UTHSCSA, BAMC
Department/Service: Medicine/Hem-Onc	Associate Investigator(s): Timothy O'Rourke, M.D. Terry Jenkins, M.D. Patrick Cobb, M.D. David A. Rinaldi, M.D. Ralph F. Heaven, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:
Number of subjects enrolled during reporting period: 0	
Total number of subjects enrolled to date: 0	
Periodic review date: Review results:	

Objective(s): 1. Primary: To determine whether a year of consolidative chemotherapy with crismatol mesylate is superior to a year of consolidative BCNU as measured by time to tumor recurrence in patients with glioblastoma multiforme. 2. Secondary: To determine whether a year of consolidative chemotherapy with crismatol mesylate is superior to a year of consolidative BCNU as measured by overall survival in patients with glioblastoma multiforme. Additional endpoints: To gather information regarding the quality of life in patients receiving consolidative chemotherapy for glioblastoma multiforme and to obtain additional safety and toxicity information on crismatol mesylate.

Technical Approach: Detailed information including preclinical studies, clinical trials, drug information, eligibility criteria, etc., included in protocol.

Progress: Accrual has been slow to this trial because of stringent eligibility criteria. Preliminary results from other centers prove that this design is feasible to complete and attempts at accrual will continue.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-148                      Status: Completed

Title: A Phase II Study of Brief Intravenous Adozelesin Infusion in Previously Untreated Advanced Cutaneous Malignant Melanoma

Start date: 8 Feb 94	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hem-Onc	Associate Investigator(s): Timothy O'Rourke, M.D. Patrick Cobb, M.D. David A. Rinaldi, M.D. Ralph F. Heaven, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 1  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To assess whether adozelesin given as a monthly intravenous infusion produces objective clinical responses in adult patients with previously untreated advanced cutaneous malignant melanoma. To determine the qualitative and quantitative toxicity and reversibility of toxicity of adozelesin administered in this fashion.

Technical Approach: Subject selection, treatment specifics, study activities/observations and further details outlined in protocol.

Progress: This trial has completed accrual. Two objective responses were observed in the first 25 patients. This level of activity was insufficient to proceed to the second phase of the study.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-149                      Status: Completed

Title: Phase II Study of Brief Intravenous Adozelesin Infusion in Previously Untreated -- Metastatic Gastric Adenocarcinoma

Start date: 8 Feb 93	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hem-Onc	Associate Investigator(s): Timothy O'Rourke, M.D. Terry Jenkins, M.D. Patrick Cobb, M.D. David A. Rinaldi, M.D. Ralph F. Heaven, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
Total number of subjects enrolled to date: 1  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To assess whether adozelesin given as a monthly intravenous infusion produces objective clinical responses in adult patients with previously untreated locally advanced or metastatic gastric adenocarcinoma. To determine the qualitative and quantitative toxicity and reversibility of toxicity of adozelesin administered in this fashion.

Technical Approach: Study design, patient selection, treatment plan and further specifics are outlined in protocol.

Progress: This study has completed accrual. Toxicities centered around myelosuppression. Two objective responses were observed in the first 25 patients, and this level of activity was insufficient to proceed to the second phase of the trial.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-151                      Status: Ongoing

Title: Phase I Oral Bioavailability Study of Topotecan

Start date: 18 Apr 94	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hem-Onc	Associate Investigator(s): Timothy O'Rourke, M.D. Terry Jenkins, M.D. Patrick Cobb, M.D. David A. Rinaldi, M.D. Ralph F. Heaven, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 5  
 Total number of subjects enrolled to date: 5  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): Characterize the bioavailability of topotecan following single oral administration compared to a single intravenous infusion. Determine the approximate bioequivalent oral to intravenous dose for topotecan. Assess the antitumor activity of topotecan.

Technical Approach: Pharmaceutical data, patient eligibility criteria, exclusion criteria, treatment plan and further specifics are outlined in protocol.

Progress: This study is nearing completion. Pharmacokinetic results indicate that topotecan has good absorption orally, as well as a prolonged half-life by that route of administration. Responses have been observed in patients with ovarian and non-small cell lung cancer.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-153                      Status: Ongoing

Title: An Open-Label, Multicenter, Non-Comparative, Study of Topotecan as Single Agent, Second-Line Therapy (Administered Intravenously as Five Daily Doses Every 21 Days) in Patients with Small Cell Lung Cancer

Start date: 25 Jul 94	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hem-Onc	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Review results:

Objective(s): To evaluate the response rate, response duration, and survival in patients with advanced small cell lung cancer who are either refractory or potentially sensitive to first-line chemotherapy and are treated with single agent topotecan administered as five daily 30 minute infusions every 21 days. Secondary: To evaluate the time to response, time to progression, and symptoms of disease in patients with advanced SCLC treated with topotecan administered on this schedule. To evaluate the qualitative and quantitative toxicities of topotecan administered on this schedule.

Technical Approach: Study design overview, population, conduct of the study, screening evaluation and other specifics are outlined in protocol.

Progress: This study has recently opened to accrual. No patients have been enrolled to date and no preliminary results are available from other centers.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-154                      Status: Ongoing

Title: Navelbine Treatment IND for Patients with Unresectable Stage II or IV Non-Small Cell Lung Cancer

Start date: 25 Jul 94	Estimated completion date:
Principal Investigator: Howard A. Burris, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hem-Onc	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 0  
Periodic review date: Review results:

Objective(s): To make intravenous NAVELBINE available to patients with unresectable Stage III or IV NSCLC who are not candidates for more aggressive local therapy while the FDA reviews the safety and efficacy of intravenous NAVELBINE for treatment of patients with advanced NSCLC. Patients with unresectable Stage III NSCLC are to be treated with NAVELBINE plus cisplatin. Stage IV patients may be treated with single-agent NAVELBINE or NAVELBINE plus cisplatin depending upon patient and physician choice. To gather additional information on the safety profile of weekly intravenous NAVELBINE therapy. To monitor response to treatment, time-to-disease progression and survival time of patients treated with intravenous NAVELBINE on a weekly schedule.

Technical Approach: Study design, general study procedures, drug administration, dose modifications, and other specifics are outlined in protocol.

Progress: This compassionate use protocol will remain open until Navelbine is officially approved by the FDA. Patients continue to benefit from the use of Navelbine in this disease.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-155                      Status: Ongoing

Title: Postural Changes in Atrial Filling Fraction with Congestive Heart Failure: An Echocardiographic Assessment

Start date: 26 Sep 94	Estimated completion date:
Principal Investigator: Michael Kwan, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Cardiology	Associate Investigator(s): David M. Mego, M.D. Bernard J. Rubal, Ph.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1. To assess atrial function using Doppler echocardiography in decompensated congestive heart failure patients. 2. To compare changes in atrial function in the supine and 80° upright tilt positions as assessed by E and A wave magnitudes, E to A wave ratios, atrial filling fraction, atrial filling force, deceleration time, isovolumic relaxation time, and left atrial size. 3. To assess atrial function using Doppler echocardiography in these same patients after medical management and return to compensated CHF. 4. To compare postural changes in atrial function in age-matched subjects without a history of documented cardiovascular disease.

Technical Approach: Medical application and methods are outlined in protocol.

Progress: This is a new study. No reportable data.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-158                      Status: Ongoing

Title: Correlation of Liver Histopathologic Findings with Hepatic Clearance of Caffeine

Start date:	Estimated completion date: 3 yrs
Principal Investigator: Timothy P. Pfanner, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Gastroenterology	Associate Investigator(s): Israel Crespo, M.D. Thomas Brewer, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To correlate hepatic function as measured by caffeine clearance with liver histopathologic changes in all patients in whom present for liver biopsy. To compare the correlation coefficient of caffeine clearance and standard liver function tests to liver histology. To determine if caffeine clearance is a reflection of liver histopathologic findings.

Technical Approach: 50 subjects will be enrolled in the study. All patients presenting to the GI clinic in whom liver biopsy is indicated will be offered the opportunity to participate. A complete physical examination will be performed, and clinically indicated lab studies will be performed. Exclusion criteria include patient refusal or inability to provide informed consent, contraindication to performance of caffeine clearance (such as drug sensitivity or renal failure), pregnancy, metastatic or primary hepatic malignancy and contraindication to liver biopsy. Specifics are outlined in protocol.

Progress: This is a new study. No reportable data.



# Detail Summary Sheet

Date: 7 Nov 94      Protocol Number: C-93-35      Status: Ongoing

Title: A Comparison of Nurses' Knowledge of Alcoholism and the Care of the Alcoholic Patient

Start date: Dec 92	Estimated completion date: Apr 94
Principal Investigator: Evelyn Swenson-Britt, M.S. RN	Facility: Med Cen Hosp, SA Brooke Army Medical Center, Texas
Department/Service: Nursing	Associate Investigator(s): Gretchen Carrougher, MN, RN Jean M. Johnson, Ph.D.
Key Words:	
Cumulative MEDCASE cost: NA	Estimated cumulative OMA cost: NA

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: Total 80; 20 from BAMC  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To compare nurses' knowledge and demographic information, attitudes regarding alcoholism, cognitive understanding of the related pathophysiology, and knowledge of standards of medical and nursing care. A total of 100 nurses from four med/surg nursing units (25 per group) will be asked to participate. There will be no sex or age limitations for participation and both registered and licensed practical/vocational nurses will be included. A quasi-experimental research design, similar to the Solomon Four Group design will be utilized to determine if the educational intervention provided has an impact on nurses' knowledge of alcoholism and the care of the alcoholic patient.

Technical Approach: The hypothesis including description of subjects, inclusion/exclusion criteria, experimental design/methods, data collection and specifics included in protocol.

Progress: Investigator did not provide an annual report. Exact status of protocol is unknown.

# Detail Summary Sheet

Date: 1 Dec 94 Protocol Number: C-94-12 Status: Ongoing

Title: Intravenous Site Location and Patency Among Pediatric Patients Less Than One Year Old

Start date: Oct 93	Estimated completion date:
Principal Investigator: Glenn R. Fernandes, AN	Facility: Reynolds ACH & Brooke Army Medical Center, Texas
Department/Service: Nursing	Associate Investigator(s): Roger Anderson, AN Patti Vincent, AN Peggy Rice, AN
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine the relationships among four traditional IV site locations and patency in pediatric patients less than one year old.

Technical Approach: The hypothesis, variables, sampling plan, design, methods and detailed specifics are outlined in protocol.

Progress: This is a new study. There is no data to report.

# Detail Summary Sheet

Date: 1 Dec 94      Protocol Number: C-94-14      Status: Ongoing

Title: Computer Simulation Modeling Applied to Capacity Management Decision Making in a Pediatric Ambulatory Clinic

Start date: Oct 93	Estimated completion date:
Principal Investigator: James D. Odom, AN	Facility: Brooke Army Medical Center, Texas
Department/Service: Nursing	Associate Investigator(s): Lee W. Richard, AN
Key Words: consumption, utilization, optimal capacity decision, computer simulation, time-series design	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Review results:

Objective(s): 1. To identify those factors that influence resource consumption and utilization in an ambulatory pediatric clinic; and 2. To develop and test a model of optimal capacity decision making through application of computer simulation. Using a time-series design with repeated measurements process, this study will be conducted in two phases. During Phase I, aim 1 will be addressed. During Phase II, a model that can be used for effective capacity management decisions will be developed and tested.

Technical Approach: Design, study site, procedure, computer simulation software, human subjects and other specifics are outlined in protocol.

Progress: The simulation model is essentially complete. Final adjustments being made.

# Detail Summary Sheet

Date: Dec 94

Protocol Number: C-94-145

Status: Ongoing

Title: The Addition of a Sport Psychology Component to a Childbirth Education Curriculum and Its Effect on Obstetric Outcome

Start date: 20 Sep 94	Estimated completion date:
Principal Investigator: Mara D.H. Smith, MEd, CCE	Facility: Brooke Army Medical Center, Texas
Department/Service: Community Health Nursing	Associate Investigator(s): J. Mallory, COL Jean M. Johnson, PhD, RN
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To examine the relationship between the addition of sport psychology techniques to a standard childbirth education curriculum and obstetric outcome. The study will examine the outcomes of two groups of patients: a control group of primiparas who attend childbirth education classes, and receive the standard childbirth education curriculum and an experimental group who attend childbirth education classes and receive the standard childbirth education curriculum with the addition of a sport psychology component including techniques to be utilized during labor and delivery. The proposed study will attempt to answer the following question: (1) Does the addition of sport psychology techniques to a standard childbirth education curriculum effect obstetric outcome as measured by duration of labor? (2) Does the addition of sport psychology techniques to a standard childbirth education curriculum effect obstetric outcome as measured by the use of analgesia and anesthesia?

Technical approach: 1. Participants who receive the sport psychology component will have shorter labors than those who do not receive this component. 2. Participants who receive the sport psychology component, overall, will use less analgesia and anesthesia than those who do not receive this component.

Progress: This is a new study. There is no reportable study.

# Detail Summary Sheet

Date: 15 Aug 94                      Protocol Number: C-64-90                      Status: Completed

Title: The Effects of Magnesium Sulfate Tocolysis on Electrolytes and Hormones of Calcium Hemostasis.

Start date: 9 May 90	Estimated completion date:
Principal Investigator: Paul M. West, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics/Gynecology	Associate Investigator(s): Arthur S. Maslow, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 6  
 Total number of subjects enrolled to date: 28  
 Periodic review date: 20 May 91      Review results: Continue

Objective(s): 1) Establish in detail the extent of electrolyte and hormonal alterations caused by therapy with magnesium sulfate for the preterm labor versus the pre-eclamptic patient and their neonates. 2) Determine if such electrolyte and hormonal disturbances correlate with the type of intravenous fluids infused or concentration of magnesium sulfate given. 3) Demonstrate that despite probable statistically significant changes in some electrolytes and hormones, clinically significant events are extremely rare, in support of available anecdotal literature.

Technical Approach: This study will include 25-30 patients in preterm labor treated in the standard manner with magnesium sulfate. Urinary electrolytes, serum/urine osmolality, PTH, calcitonin, and anion gap will be evaluated. The control group will include 5-10 pre-eclamptic patients as positive controls and 5-10 normal patients as negative controls.

Progress: Study completed without additional patients and presented at Armed Forces District, American College of Obstetricians and Gynecologists, Seattle, WA, Nov 93.

# Detail Summary Sheet

Date: 7 Nov 94                      Protocol Number: C-93-14                      Status: Completed

Title: Determination of Excretion of Urinary Albumin, Calcium, and Total Protein in 24 Hour Urine Specimens from Healthy Pregnant Women by CPT John Phelps III

Start date: 4 Dec 92	Estimated completion date:
Principal Investigator: John Y. Phelps, III, M.D. & Ken Higby, M.D.	Facility: Univ of TX at SA Brooke Army Medical Center, Texas
Department/Service: Department Obstetrics-Gynecology	Associate Investigator(s):
Key Words:	Manuel Morales, M.D. Mark Grant, M.D. Oded Langer, M.D.
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 233

Total number of subjects enrolled to date: 235

Periodic review date: Review results:

Objective(s): To determine the excretion of albumin, calcium, and total protein in normal healthy pregnant women. After the above is established, to test the following hypothesis: (1) Microalbuminuria is a predictor of the development of preeclampsia; (2) A low calcium/creatinine ratio in urine is a predictor of the development of preeclampsia.

Technical Approach: Preeclampsia is a common disorder of pregnancy and a major cause of maternal, fetal, and neonatal mortality and morbidity. Its prevention would have a major impact on perinatal morbidity and mortality. The signs and symptoms of the disease usually present in the third trimester. However, the pathophysiologic mechanisms involved are felt to begin much earlier in pregnancy (8-18 weeks of gestation). It thus seems prudent to search for early indicators of the disease.

Progress: Project has been completed. Adequate data has been obtained and we are currently analyzing the data. Results to be published at a later date. American Journal of OB/GYN 1994.

# Detail Summary Sheet

Date: 15 Aug 94      Protocol Number: C-93-82      Status: Ongoing

Title: Simulation of Cervical Diameter Measurements: An Appraisal of Accuracy

Start date: 14 May 93	Estimated completion date: 1 Jan 94
Principal Investigator: John Y. Phelps, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Obstetrics-Gynecology	Associate Investigator(s): Michael H. Smyth, M.D. Kenneth Higby, M.D. Allan R. Mayer, D.O.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 123

Total number of subjects enrolled to date: 123

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To assess the accuracy of clinical cervical diameter measurements using cervical simulators, and to compare these results among attending obstetricians, residents of various year levels, and labor and delivery nurses. Methods and results included in protocol.

Technical Approach: Specifics outlined in protocol.

Progress: Project completed and submitted for publication. We determined accuracy to be about 90% when allowed for an error of plus-minus 1 cm and no difference in accuracy between providers with different levels of experience.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-30                      Status: Ongoing

Title: Comparison of Anti-Hypertensive Agents for Hypertensive Emergencies in Pregnancy:- A Pilot Study"

Start date: 14 Jan 94	Estimated completion date:
Principal Investigator: Kenneth Higby, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Obstetrics-Gynecology	Associate Investigator(s):
Key Words: Labetalol, clonidine, diazoxide, nifedipine	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): Since Apresoline is no longer being manufactured by Ciba-Geigy it is necessary to look at alternative forms of therapy for hypertensive emergencies in pregnancy. Desire to determine which agent (labetalol, clonidine, diazoxide, nifedipine) is most effective and has the least adverse effects upon patients. This has not been evaluated to date.

Technical Approach: Study design, study outcome monitors, sample size, subject population, etc. outlined in protocol.

Progress: We have not enrolled any protocols to date. There were some initial problems attaining the drugs as ward stock from the pharmacy but this is being resolved. Hopefully patients will be recruited soon.



# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-45                      Status: Ongoing

Title: Timing the Postcoital Test: Use of a Home Urinary LH Test Versus Traditional Methods

Start date: 7 Feb 94	Estimated completion date:
Principal Investigator: Mark Marconi, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Obstetrics-Gynecology	Associate Investigator(s):
Key Words: postcoital, BBT charts, home urinary LH test	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine if use of a home urinary LH test improves the accuracy of timing the postcoital test, compared with traditional timing methods such as BBT charts & menstrual history.

Technical Approach: This study is designed to test whether home urinary LH determination improves the timing of postcoital testing, as compared with BBT charts and menstrual history. The patients to be studied will be infertile couples presenting to BAMC E&I clinic for initial infertility evaluation. Female subjects included will be between the ages of 18 & 40 with regular cycles with menses every 21-35 days and have ovulation confirmed by a d21 progesterone level >4 ng/ml. Exclusion criteria will include treatment with clomid or pergonal, lower genital tract infection, oligo- or azospermia, cervical anomalies, prior cervical surgery, & history of cervical factor infertility. The number of subjects required is 25. Further details in protocol.

Progress: Investigator did not provide a report. Status of study is unknown.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-50                      Status: Ongoing

Title: The Effect of Subcutaneous Terbutaline Therapy on Glucose Tolerance in Pregnancy as Assessed by a Modified Bergman's Minimal Model

Start date: 7 Feb 94	Estimated completion date:
Principal Investigator: Craig E. McCoy, D.O.	Facility: Brooke Army Medical Center, Texas
Department/Service: Obstetrics-Gynecology	Associate Investigator(s):
Key Words: Terbutaline, pathophysiologic, terbutaline-induced	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:
Number of subjects enrolled during reporting period: <u>2</u>	
Total number of subjects enrolled to date: <u>2</u>	
Periodic review date: _____ Review results: _____	

Objective(s): To elucidate the pathophysiologic effects of terbutaline-induced changes in carbohydrate metabolism.

Technical Approach: Hypothesis is that subcutaneous Terbutaline has no significant effect on glucose metabolism.

Progress: Haven't gotten the patients to qualify as candidates. Plan to continue.

# Detail Summary Sheet

Date: 1 Dec 94 Protocol Number: C-94-63 Status: Ongoing

Title: Evaluation of the Safety and Effectiveness of HAL-C™ Coating Solution (Sodium Hyaluronate Solution in Surgery)

Start date: 11 Mar 94	Estimated completion date: 31 Dec 94
Principal Investigator: Dan Gehlbach, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Obstetrics-Gynecology	Associate Investigator(s):
Key Words: adjuvant, serosal, de novo, postsurgical, sodium hyaluronate, phosphate buffered saline, adhesions	
Cumulative MEDCASE cost: None	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 6  
Total number of subjects enrolled to date: 6  
Periodic review date: Review results:

Objective(s): To evaluate the safety and effectiveness of HAL-C™ as a surgical adjuvant when used to coat serosal tissues thereby reducing the incidence, and/or severity, and/or extent of postsurgical de novo adhesions. Two different concentrations of HAL-C™, 0.2% and a 0.4% solution of sodium hyaluronate (w/w), will be compared to a control solution, phosphate buffered saline, referred to as PBS in this protocol.

Technical Approach: This multi-center study is designed as a three-way, randomized, double blind, safety and effectiveness study. Patients will be randomized to receive one of the following test solutions:

0.2% HAL-C™ - treatment

0.4% HAL-C™ - treatment

Phosphate buffered saline (PBS) - control

The study will be conducted at up to fifteen investigational sites. Multiple applications of the study solution will be made during each initial surgical procedure. Safety data will be evaluated from baseline through one month following the initial surgery. Effectiveness will be determined by comparing the incidence, severity, and extent of postsurgical adhesions present at baseline and at the time of a scheduled (second-look) surgery among the three groups. Further specifics ref inclusion/exclusion criteria, methodology, etc. given in protocol.

Progress: Still enrolling patients.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-92                      Status: Ongoing

Title: Sterilization Regret in a Military Population

Start date: 11 Apr 94	Estimated completion date:
Principal Investigator: Stacey Thornton, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Obstetrics/Gynecology	Associate Investigator(s): Dan Gehlbach, M.D. Lauren Gehlbach, RN, MS, CNS
Key Words: sterilization, tubal ligation reversal	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): Among women in a military population who seek reversal of tubal ligation, to determine what factors they identify as responsible for their desire to overturn a permanent procedure.

Technical Approach: A questionnaire will be administered to three groups of women (1) women currently seeking reversal of tubal ligation (approx 75), (2) women who have undergone tubal reanastomosis at BAMC in the past two years (approx 100), and (3) women of age 25-40 with a tubal ligation who are not interested in sterilization reversal (approx 100). Questionnaire will have 17 questions from five different categories: (1) Counseling - Physician Behavior, (2) Counseling - Patient Behavior, (3) Expectations, (4) influences, and (5) Economics. It will contain no patient identifiers and the patients will be counseled that their responses will not influence their medical care or chance for sterilization reversal. Further specifics and statistic input is outlined in protocol.

Progress: Data collection still in progress.

# Detail Summary Sheet

Date: 15 Aug 94      Protocol Number: C-93-13      Status: Ongoing

Title: Islet Cell Hyperplasia of the Pancreas in Adults: An Immunohistochemical and Morphometric Study

Start date: 4 Dec 92	Estimated completion date: 4 Dec 94
Principal Investigator: Melton H. Fish, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Pathology	Associate Investigator(s): M. H. Enghardt, M.D. J. I. Smith, M.D. K. J. Carlin, M.D. I. A. Chapa, MT E. Ayala, MA
Key Words: Islet cell hyperplasia, pancreas, nesidioblastosis, hyper insulinemia	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: N/A  
 Total number of subjects enrolled to date: N/A  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine whether or not the pancreatic endocrine volume - measured as area of endocrine tissue and expressed as a percentage of total glandular area - in two BAMC cases of patients with hyperinsulinemic hypoglycemia differs significantly from the relative endocrine volume in pancreata for age- and sex-matched controls. In contradistinction to the studies which disclaim an increase of endocrine volume, we hypothesize that one is present in our cases.

It is necessary to address a thorough review of the world's literature in order to completely document experience with diagnosis and with both medical and surgical therapy of hyperinsulinemic hypoglycemia caused by nesidioblastosis/islet cell hyperplasia. Modes of therapy and their outcome from all reported cases in adults, including our own, will be tabulated and evaluated.

Technical Approach: Archival tissue from two patients. Control tissues from age and sex matched control pancreata obtained via South Texas Organ Bank. Animal studies not required.

Progress: Awaiting set-up of color imaging system.

# Detail Summary Sheet

Date: 27 Oct 94      Protocol Number: C-93-116      Status: Ongoing

Title: Development of a Synthetic Biologic Control for Immunohistochemical Procedures

Start date: Aug 93	Estimated completion date:
Principal Investigator: Michael H. Enghardt, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Pathology and Area Laboratories	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): Design and manufacture a semisynthetic tissue control using red cell membranes, latex granules and purified antigen.

Technical Approach: Pig blood will be used as the source of red cells. Blood may be collected from any pig that is on a terminal study and is a part of an approved animal use protocol. The blood will be collected while the animal is anesthetized, just prior to euthanasia. Further details in protocol.

Progress: Tests in progress in Dept of Clinical Investigation. Patent application pending.

# Detail Summary Sheet

Date: 15 Aug 94                      Protocol Number: C-79-87                      Status: Ongoing

Title: Appetite and Pectin.

Start date: 9 Sep 87	Estimated completion date:
Principal Investigator: Chandra M. Tiwary, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words: Appetite Obesity	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 23  
Total number of subjects enrolled to date: 131

Periodic review date: 14 May 91                      Review results: Continue

Objective(s): 1) To determine if specific dietary modifications can result in improved weight reduction in certain categories of obese children.

Technical Approach: Subjects will be obese children (ages 6-18) attending the pediatric clinic. All subjects will be studied twice at least 3 days apart. Subjects will be given either orange juice or orange juice with pectin. The child will be asked to describe the degree of hunger on a scale of 1 to 20, giving a rating of 1 if most full and 20 if very hungry. The same scale will be used to rate hunger every hour for four hours. At the end of four hours, the child will be given ice cream and again asked to rate hunger. Saliva production will be measured on three times - before drinking the juice, 4 hours after drinking the juice, and 1/2 hour after eating the ice cream.

Progress: Three adult patients were recruited. There was a problem in procuring pectin. When the pectin in appropriate form arrives, I will study the adult subjects. The permission to enroll adults was requested and granted by Clinical Investigation.

# Detail Summary Sheet

Date: 15 Aug 94                      Protocol Number: C-24-88                      Status: Terminated  
 Title: Ceftriaxone for Outpatient Management of Suspected Occult Bacteremia.

Start date: 13 Jan 88	Estimated completion date:
Principal Investigator: James H. Brien, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: 66 (FY 90)  
 Periodic review date: 25 May 91 Review results: Continue

Objective(s): To determine the effectiveness of ceftriaxone in the outpatient management of children three to thirty-six months of age with suspected occult bacteremia.

Technical Approach: Children are randomized to receive either ceftriaxone IM, Augmentin PO with ongoing follow-up until fever and illness is resolved.

Progress: Due to the principal investigator's reassignment to Walter Reed Army Medical Center, this project has had no patients enrolled since last review. Results have been published in a manuscript to the Pediatric Infectious Disease Journal, 1993. This study should be terminated.



# Detail Summary Sheet

Date: 15 Aug 94      Protocol Number: C-90-88      Status: Terminated

Title: Phase I Study of Piritrexim in Children with Advanced Leukemia and Solid Tumors (A Multicenter Study under the Direction of Dr. Thomas E. Williams, Santa Rosa Childrens Hospital).

Start date: 22 Nov 88	Estimated completion date:
Principal Investigator: Allen R. Potter, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Timothy J. O'Rourke, LTC, MC
Key Words: Leukemia	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: 25 Feb 91 Review results: Continue

Objective(s): To define the maximum tolerated dose and the dose limiting toxicity when Piritrexim capsules are administered orally to children in a daily x 5 schedule repeated every three weeks.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: The study closed with no patients enrolled.

# Detail Summary Sheet

Date: 19 Oct 94                      Protocol Number: C-37-90                      Status: Terminated

Title: The Incidence of Congenital Respiratory Syncytial Virus.

Start date: 12 Mar 90	Estimated completion date:
Principal Investigator: LTC Howard S. Heiman, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): MAJ Thomas Perkins, MC CPT Michael Battista, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_

Total number of subjects enrolled to date: \_\_\_\_\_

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): A prospective study to determine if respiratory syncytial virus can be transmitted congenitally, and the incidence of RSV in the newborn population. Study population will include all women who deliver at Brooke Army Medical Center and their newborns, both term and premature.

Technical Approach: All newborns will receive routine DeLee suctioning of oral and nasopharynx on the perineum or abdomen by obstetrics. The specimen will be sent to the area lab for RSV ELISA. On all newborns who are RSV ELISA positive acute and convalescent serum titers for RSV will be obtained.

Progress: There have been no patients entered on this protocol. There has been no interest in pursuing this study since the departure of the principal investigator.

# Detail Summary Sheet

Date: 7 Nov 94	Protocol Number: C-62-90	Status: Ongoing
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Title: High-Dose Chemotherapy with Autologous Bone Marrow Rescue in Children with Recurrent or Progressive Solid Tumors or Primary CNS Malignancies: A Phase II Study (Collaborative Study with Walter Reed Army Medical Center).

Start date: 15 May 90	Estimated completion date:
Principal Investigator: Allan R. Potter, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Glenn Edwards, MAJ, MC, WRAMC David Maybee, COL, MC, WRAMC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: <u>1</u>
Total number of subjects enrolled to date: <u>1</u>
Periodic review date: <u>20 May 90</u> Review results: <u>Continue</u>

Objective(s): 1) To define the toxicities of a regimen of high-dose cyclophosphamide (CY), etoposide (VP-16), and carboplatin (CBDCA) with autologous bone marrow infusion in pediatric patients with recurrent or progressive CNS neoplasms or solid tumors.

2) To measure response rates in a group of patients with refractory solid tumors and CNS malignancies following high-dose chemotherapy and autologous bone marrow infusion.

Technical Approach: To be eligible for this study, patients must be < 21 years of age, have an estimated survival of at least 8 weeks, and have adequate blood counts prior to bone marrow harvest. Therapy will follow the schema outlined in the study protocol.

Progress: Study still continuing. No reportable data as of this date.

# Detail Summary Sheet

Date: 15 Aug 94 Protocol Number: C-32-91 Status: Completed

Title: Evaluation of Cisapride (R 51,619) in Patients with Gastrointestinal Motility Disorders.

Start date: 20 Feb 91	Estimated completion date:
Principal Investigator: Judith O'Connor	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: 1  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine the effect of cisapride on the symptoms of unexplained upper abdominal pain, nausea, vomiting, anorexia, early satiety, bloating/distension in patients with gastrointestinal motility disorders.

Technical Approach: The patient will receive cisapride tablets or suspension 50 mg tid for six weeks. If improvement is observed, the patient may continue to receive cisapride on a long-term basis for up to 48 months.

Progress: Study on protocol with Janssen Pharmaceuticals is completed. Data collection is progress.

# Detail Summary Sheet

Date: 15 Aug 94 Protocol Number: C-92-2 Status: Ongoing

Title: Childhood Obesity: Incidence Density Among Childhood Military Dependents and Association of Obesity with the Duty Status of the Sponsor

Start date: Feb 92	Estimated completion date:
Principal Investigator: COL Chandra Tiwary, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words: Childhood Obesity Incidence, Duty Status	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1500

Total number of subjects enrolled to date: 2000

Periodic review date: Review results:

Objective(s): To describe the incidence density of childhood obesity among the dependents of US Army personnel. The association between incidence of obesity and the active duty or retiree status of the sponsor will also be assessed.

Technical Approach: All children beyond the age of 1 year attending the pediatric and adolescent clinic of the Brooke Army Medical Center will be included in this study. Their order of birth, name, gender, date of birth/age, height, weight, the sponsor's social security number, rank, duty status (active duty or retired), year when retired from the military, age on retirement and the current age will be recorded.

Progress: Approximately 1500 children who attended this pediatric clinic had their forms filled out. About 470 charts have been entered in the database in a computer, we will analyze the data when all the forms have been entered in database. We still need a data entry person for about two weeks time.

# Detail Summary Sheet

Date: 15 Aug 94                      Protocol Number: C-92-82                      Status: Completed

Title: Blood Lead (Pb) Levels in Infants and Toddlers

Start date: Sep 92	Estimated completion date: '94
Principal Investigator: CPT Deborah Baumann, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Pediatrics	Associate Investigator(s): LTC Allan Potter, MC Gea Miller, M.D. COL John D. Roscelli, MC
Key Words: Lead	
Cumulative MEDCASE cost: No additional funds	Estimated cumulative OMA cost: No additional funds
Number of subjects enrolled during reporting period: 810	
Total number of subjects enrolled to date: 1142	
Periodic review date: 22 Mar 93	Review results:

Objective(s): To ascertain the incidence of lead exposure in the military dependents attending 6, 12, and 24 month well baby clinics. We will screen the children with a 5-part questionnaire. Any 6-month old infant found to be at risk for Pb exposure based on answers to their questionnaire will receive a blood lead level. All 12 and 24 month old children will receive a blood lead level in combination with a questionnaire. The infants will receive followup care at Brooke Army Medical Center (BAMC) based on blood lead results to include: education on sources of Pb exposure, environmental evaluations, dietary modification, medical evaluations, and chelation therapy if needed.

Technical Approach: We propose a descriptive study to investigate the incidence of lead exposure in military dependents.

Progress: This study is complete. It was Dr. Baumann's residency paper. Manuscript is being submitted for publication.

# Detail Summary Sheet

Date: 25 Oct 94      Protocol Number: C-93-09      Status: Ongoing

Title: Extracellular Fluid Volume Loading and Prevention of Amphotericin B Nephrotoxicity

Start date: 19 Oct 92	Estimated completion date:
Principal Investigator: Luisa Gomez, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Pediatrics	Associate Investigator(s): John Roscelli, M.D. Theodore Cieslak, M.D. Martin Weise, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 19  
 Total number of subjects enrolled to date: 19  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To study the effects of acute extravascular fluid volume expansion at the time of Amphotericin B administration on the prevention of Amphotericin B induced nephrotoxicity in patients less than 23 years of age. The study will be randomized, nonblinded and prospective.

Technical Approach: All pediatric patients <23 years of age who require Amphotericin B for suspected or proven deep mycosis will be eligible for the study. Patients excluded from the study will include those with known cardiac disease and those with significant renal disease - specifically a creatinine clearance of <50 ml/min per 1.73 m<sup>2</sup>. Calculated sample size for statistical significance is based on having an 80% chance of detecting an 80% reduction in the previously described 80% incidence of azotemia in the control group. This will require a sample size of 20 patients including 10 patients in the control group and 10 patients in the study group.

Progress: Patient accrual and data collection still in process.

# Detail Summary Sheet

Date: 19 Oct 94      Protocol Number: C-93-61      Status: Ongoing

Title: Low-Volume vs High-Volume Blood Culture Sampling in Immunocompromised Children

Start date: 23 Dec 92	Estimated completion date:
Principal Investigator: Theodore J. Cieslak, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): It has previously been suggested that low-volume blood culture sampling is adequate to detect most cases of bacteremia in children. Recent studies, however, demonstrate that large proportion of sepsis in immunocompromised children involves low microbial colony counts. This study will prospectively seek to determine whether high-volume blood sampling for culture will significantly improve the ability to detect bacteremia in this group of children.

Technical Approach: Specifics outlined in protocol.

Progress: The principal investigator has been deployed to Panama. The exact status of this protocol is unknown.



# Detail Summary Sheet

Date: 15 Aug 94      Protocol Number: C-93-121      Status: Ongoing

Title: Exogenous Surfactant Therapy in Premature Infants: A Multicenter Trial

Start date: 21 Jun 93	Estimated completion date:
Principal Investigator: Howard S. Heiman, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Pediatrics	Associate Investigator(s): Deborah J. Leander, R.N. Joanna C. Beachy Barbara S. Turner William Dean Glover
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): The leading cause of death for prematurely born infants born in the US is Respiratory Distress Syndrome (RDS). Specific aims of this study are to incorporate findings from the current study and extend knowledge on exogenous surfactant types of exogenous surfactant (Exosurf & Survanta), three methods of administration (Sideport adapter, feeding tube, and double lumen endotracheal tube) and the resulting neonatal physiologic responses and outcomes. Secondary aim will be to determine the relationships between type of surfactant and administration technique, nursing assessed neonatal clinical cues of a hemodynamically significant patent ductus arteriosus, and neonatal outcomes.

Technical Approach: Hypothesis, synopsis, nursing/medical applications, status, study plan, and specifics outlined in protocol.

Progress: The patients have tolerated the study procedures well. There have been no complications. They have responded positively to the surfactant given by the different methods. The results are under analysis at Madigan Army Medical Center. We have requested an extension on the use of FY 94 funds through March of 1995.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-03                      Status: Ongoing

Title: Growth and Endocrine Function in Children After Bone Marrow Transplantation

Start date: 19 Oct 93	Estimated completion date:
Principal Investigator: David A. Nickels, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Pediatrics	Associate Investigator(s): Terry Pick, M.D. Allen Potter, M.D.
Key Words: pubertal development, endocrine function, BMT	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 16  
 Total number of subjects enrolled to date: 16  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To prospectively study the effect of BMT on growth, pubertal development, and endocrine function in children undergoing BMT at BAMC.

Technical Approach: Study design; data collection/methods; statistical analysis and specifics are included in protocol.

Progress: Sixteen patients have been enrolled in the protocol in the first year to date. Patients are to be reassessed every six months as to their growth and endocrine function, so very little follow-up data has been collected at this point, and no statistical analysis is possible at this time. Patients will continue to be enrolled and follow-up studies will be obtained as detailed in the protocol. One problem to be overcome is that many of the patients come to BAMC from a great distance for their BMT procedure and then receive their ongoing follow-up care at another medical center closer to where they live. We are attempting to coordinate with the distant sites to obtain the patient's studies locally if they are not returning to BAMC at regular intervals.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-06                      Status: Ongoing

Title: Immunologic Characterization of Coagulase-Negative Staphylococci

Start date:	Estimated completion date:
Principal Investigator: Theodore J. Cieslak, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Pediatrics	Associate Investigator(s): Stephen M. Dentler, M.D. Michael A. Battista, M.D. Howard S. Heiman, M.D. Gerald W. Fischer, M.D.
Key Words: Staphylococci, virulence, commensal strains, serotype	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To assess the role of coagulase-negative staphylococcal serotype-specificity with respect to virulence. We hypothesize that only serotype II CNS strains are true human pathogens, while commensal strains may be of any serotype. We propose to demonstrate this by comparing commensal and pathogenic strains by means of a simple test of proportions.

Technical Approach: Medical applications, status, proposal, methods including statistical analysis and further details are outlined in protocol.

Progress: Investigator did not provide an annual report. Exact status of protocol is unknown.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-17                      Status: Ongoing

Title: Electrocardiographic Voltage Criteria Are Too Sensitive for Left Ventricular Hypertrophy in Children

Start date: 13 Dec 93	Estimated completion date:
Principal Investigator: Patrick Glasow, M.D.	Facility: Ft Sill & Brooke Army Medical Center, Texas
Department/Service: Pediatrics	Associate Investigator(s):
Key Words: left ventricular hypertrophy (LVH)	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 22  
 Total number of subjects enrolled to date: 22  
 Periodic review date: Review results:

Objective(s): To assess the clinical effectiveness of electrocardiographic (EKG) voltage criteria for detecting left ventricular hypertrophy (LVH), and test efficacy of repeating EKGs prior to proceeding to more expensive tests.

Technical Approach: Subject population will be all pediatric patients (age birth - 23, male and female) referred to BAMC pediatric cardiology for possible LVH on EKG (except those with left bundle branch block previously known structural congenital heart disease). The study size will be approximately 100 patients.

Progress: Original PI Michael Serwacki, M.D., is continuing study at Fort Sill and Dr. Glasow is assuming study at BAMC. Significant findings indicate study should be continued.

# Detail Summary Sheet

Date: 1 Dec 94      Protocol Number: C-94-67      Status: Ongoing

Title: Multicenter Double-Blind, Study of Fluconazole in the Early Empirical Treatment of Suspected Fungal Infections in Febrile Neutropenic Patients Undergoing therapy for Cancer

Start date: 22 Mar 94	Estimated completion date:
Principal Investigator: Theodore J. Cieslak, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Pediatrics	Associate Investigator(s):
Key Words: Fluconazole, empirical, fungemia, febrile, neutropenic, granulocytopenia, visceral	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine the efficacy and safety of early systemic empiric therapy with fluconazole for the treatment of suspected fungal infections complicating granulocytopenia. (Suspected Fungal Infection is defined as new fever with neutropenia. Proven Fungal Infection is defined as culture and/or biopsy documented invasive fungal infection, esophageal candidiasis, fungemia, or deep visceral fungal infection [e.g., hepatosplenic candidiasis]. To determine if fluconazole decreases the need for administration of amphotericin B [including both empiric and therapeutic use]. To determine the influence of fluconazole on patterns of fungal colonization and acquisition during the neutropenic period. To determine the effect of fluconazole on endogenous and acquired fungal flora as measured by the in vitro susceptibility of colonizing and infecting fungi before, during and after administration of fluconazole. Following their episode of granulocytopenia, study patients will be followed for 14 days to determine if early Fluconazole empiric therapy has an effect on survival of cancer patients with fever and neutropenia.

Technical Approach: Study design, patient selection, management of study medication and other specifics are outlined in protocol.

Progress: Investigator did not provide an annual report. Exact status of protocol is unknown.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-101                      Status: Ongoing

Title: Effect of Exercise on Blood Glucose Level Among Children with Insulin Dependent Diabetes Mellitus (IDDM)

Start date: 31 May 94	Estimated completion date:
Principal Investigator: Chandra M. Tiwary, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Pediatrics	Associate Investigator(s):
Key Words: diabetes mellitus, plasma, ketones	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:
Number of subjects enrolled during reporting period: 5	
Total number of subjects enrolled to date: 5	
Periodic review date: Review results:	

Objective(s): To define the effect of exercise on the blood sugar level of the child with IDDM. To find the effect of exercise on plasma and urinary ketones in children with IDDM.

Technical Approach: The effect exercise has on the blood glucose level in a child with IDDM may, once defined, be used to prescribe a regular program of physical fitness for the child with IDDM. This knowledge may also be utilized to treat the diabetic child who develops mild hyperglycemia with decreased insulin than might otherwise be required.

Progress: Five children and adolescents with diabetes have been enrolled in the study. The laboratory values are not available in all children. The results have not been analyzed, it appears that in some children the blood glucose falls after the exercise.

# Detail Summary Sheet

Date: 1 Dec 94      Protocol Number: C-94-124      Status: Ongoing

Title: Epidemiologic Study of Cystic Fibrosis (ESCF)

Start date:	Estimated completion date:
Principal Investigator: Stephen C. Inscore, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Pediatrics	Associate Investigator(s): H. Joel Schmidt, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:
Number of subjects enrolled during reporting period: 20	
Total number of subjects enrolled to date: 20	
Periodic review date: Review results:	

Objective(s): To longitudinally characterize the variability in and monitor the decline of pulmonary function in CF patients and relate these characteristics to corresponding population factors including age, gender, CF genotype, and organisms infecting the respiratory tract. To longitudinally characterize the rate of pulmonary exacerbations requiring specific antibiotic therapy in CF patients and relate these exacerbations to corresponding population factors including age, gender, CF genotype, and organisms infecting the respiratory tract. To collect information on the safety of long-term treatment with Pulmozyme (dornase alfa) and to examine trends in pulmonary function and rates of pulmonary exacerbations that relate to the effectiveness of long-term treatment with Pulmozyme.

Technical Approach: Patient criteria, study design, evaluations, statistical analysis and further specifics are outlined in protocol.

Progress: Too early for preliminary conclusions. Initial results will be reported this fall at National LCF Conference in Orlando, FL, as a part of the National Data Collection for the ESCF study.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-140                      Status: Ongoing

Title: A Six Month Randomized, Parallel Group, Double-Blind Clinical Trial Comparing Amiloride Hydrochloride with Placebo in Adolescent and Adults with Cystic Fibrosis

Start date: 29 Aug 94	Estimated completion date:
Principal Investigator: Stephen C. Inscore, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To compare the efficacy of nebulized amiloride hydrochloride 4.5 mg (4.5 ml of 1 mg/ml, QID) with placebo in the treatment of adult and adolescent patients with mild to moderate cystic fibrosis. The primary efficacy assessment will be the decline in pulmonary function over the duration of the trial. To compare the quality of life as assessed by the Quality of Well-Being Scale and the MOS Short-form 36 of amiloride-treated vs placebo-treated adult and adolescent patients with mild to moderate cystic fibrosis. To compare the safety profile of nebulized amiloride hydrochloride 4.5 mg (4.5 ml of 1 mg/ml, QID) with placebo in the treatment of adult and adolescent patients with mild to moderate cystic fibrosis. Safety assessments will include clinical laboratory tests and collection of adverse events.

Technical Approach: Study procedures, data procurement/analysis, clinical supplies, investigator's obligations and specifics are outlined in protocol.

Progress: This is a new study. There is no reportable data.



# Detail Summary Sheet

Date: 25 Oct 94                      Protocol Number: C-48-90                      Status: Terminated

Title: Evaluation of a Novel Aminoglycoside Dosing Nomogram.

Start date: 27 Mar 90	Estimated completion date:
Principal Investigator: Thomas C. Shank, CPT, MS	Facility: Brooke Army Medical Center, Texas
Department/Service: Pharmacy Service	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:
Number of subjects enrolled during reporting period: <u>1</u>	
Total number of subjects enrolled to date: <u>7</u>	
Periodic review date: <u>n/a</u> Review results: _____	

Objective(s): To evaluate the predictive accuracy of a novel aminoglycoside dosing nomogram.

Technical Approach: Adult male and female patients who have an infection requiring gentamicin will be admitted to the study. When the patients' serum gentamicin level has reached steady state, one of the study participants will administer one dose of gentamicin via a syringe pump and draw both nadir (trough) and peak serum gentamicin samples. Each sample will be divided into two parts, one will be sent to the DPALS laboratory for routine analysis and the other will be analyzed in DCI by one of the study participants.

Progress: No new patients have been enrolled in this protocol; therefore, it is requested that this study be terminated.

# Detail Summary Sheet

Date: 15 Aug 94      Protocol Number: C-93-123      Status: Terminated

Title: WAIS-R/WAIS-III Clinical Pilot Comparison

Start date: Jun 93	Estimated completion date: Dec 94
Principal Investigator: Pamelia Clement, Ph.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Psychiatry	Associate Investigator(s):
Key Words: Head Injury	
Cumulative MEDCASE cost: 0	Estimated cumulative OMA cost: 0

Number of subjects enrolled during reporting period: 3  
Total number of subjects enrolled to date: 3  
Periodic review date: 31 Dec 93      Review results: Not yet reviewed

Objective(s): To determine if head injured subjects who are administered WAIS-R respond to selected WAIS-III clinical pilot items in a corresponding manner.

Technical Approach: Approximately 30 subjects will be required, consisting of individuals diagnosed within the criteria listed below:

Progress: Due to the need to devote neuropsychological resources to the GWI evaluation project, this study has been discontinued. It will not be renewed.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-11                      Status: Terminated

Title: Assessment of AIDS Risk and Implications for Prevention

Start date: Oct 93	Estimated completion date:
Principal Investigator: David Orman, M.D.	Facility: Darnall ACH & Brooke Army Medical Center, Texas
Department/Service: Psychiatry	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): The purpose of the study is to: 1) Describe the distribution of HIV-risk behaviors and concomitant factors. Individual factors to be investigated include HIV/AIDS attitudes, knowledge, personality factors, psychological distress-related symptomatology, level of self-esteem, general problem-solving skills, as well as amount of adherence to traditional gender roles in an identifiability high-risk (confirmed STD) demographically diverse sample; 2) Develop and validate an HIV/AIDS attitude, knowledge, and high-risk behavior inventory; 3) Determine the variables that best predict self-reported HIV-risk behavior in this sample for use in proposing a targeted intervention for sexually active individuals; 4) Identify variables that best predict objective behavior change and relapse as indicated by individual reinfection (to be monitored on a monthly basis for six months). Further details included in protocol.

Technical Approach: As outlined in protocol.

Progress: This protocol was terminated secondary to the loss of graduate student support in the Spring of '94.

# Detail Summary Sheet

Date: 1 Dec 94 Protocol Number: C-94-11 Status: Terminated

Title: Assessment of AIDS Risk and Implications for Prevention

Start date: Oct 93	Estimated completion date:
Principal Investigator: David Orman, M.D.	Facility: Darnall ACH & Brooke Army Medical Center, Texas
Department/Service: Psychiatry	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): The purpose of the study is to: 1) Describe the distribution of HIV-risk behaviors and concomitant factors. Individual factors to be investigated include HIV/AIDS attitudes, knowledge, personality factors, psychological distress-related symptomatology, level of self-esteem, general problem-solving skills, as well as amount of adherence to traditional gender roles in an identifiability high-risk (confirmed STD) demographically diverse sample; 2) Develop and validate an HIV/AIDS attitude, knowledge, and high-risk behavior inventory; 3) Determine the variables that best predict self-reported HIV-risk behavior in this sample for use in proposing a targeted intervention for sexually active individuals; 4) Identify variables that best predict objective behavior change and relapse as indicated by individual reinfection (to be monitored on a monthly basis for six months). Further details included in protocol.

Technical Approach: As outlined in protocol.

Progress: This protocol was terminated secondary to the loss of graduate student support in the Spring of '94.

# Detail Summary Sheet

Date: 7 Nov 94	Protocol Number: C-12-77	Status: Ongoing
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Title: Intravenous Administration of I<sup>131</sup> (NP59) for Adrenal Evaluation of Imaging.

Start date: 15 Nov 76	Estimated completion date:
Principal Investigator: Gilbert Sostre, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Radiology/Nuclear Medicine	Associate Investigator(s): Neil Katz, MAJ, MC
Key Words: Adrenal Scan	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period:	0
Total number of subjects enrolled to date:	11
Periodic review date: 16 Sep 92	Review results: Continue

Objective(s): Clinical evaluation of NP 59 as a diagnostic agent for the detection of adrenal-cortical disorders and as a potential scanning agent for detecting structural abnormalities of the adrenal medulla.

Technical Approach: This study will be performed on 50 patients after complete evaluation by the Endocrinology Service. The radiopharmaceutical will be administered by slow IV injection with a dose of 1 mCi in adults and 15 Ci/kg in children. Lugol's solution, 5 drops twice daily starting one day before injection and continuing for two weeks, will be used to block thyroid uptake of radioiodine. Images will be obtained on the 4th, 7th, and 11th day following injection using scintillation camera.

Progress: There have been no new patients enrolled since 16 September 1992. Study remains open for patient accrual.

# Detail Summary Sheet

Date: 25 Oct 94      Protocol Number: C-47-89      Status: Ongoing

Title: Evaluation of <sup>131</sup>I-miBG (<sup>131</sup>I-meta-iodobenzylguanidine sulfate) in Patients Suspected of Having Pheochromocytoma, Paraganglioma or Medullary Hyperplasia.

Start date: 20 Mar 89	Estimated completion date:
Principal Investigator: James D. Heironimus, LTC, USAF, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Dept. of Radiology/Nuclear Medicine	Associate Investigator(s): Neil Katz, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 6  
 Total number of subjects enrolled to date: 40  
 Periodic review date: 20 May 91      Review results: Continue

Objective(s): To evaluate the use of <sup>131</sup>I-miBG as an aid in the diagnosis, evaluation, and localization of pheochromocytomas, paraganglioma, neuroblastoma and/or adrenal medullary hyperplasia.

Technical Approach: Patients suspected of having pheochromocytoma, paraganglioma or medullary hyperplasia will be eligible. If upon careful consideration of the clinical history, examination and laboratory findings the patient is considered to have reasonable suspicion (>5% possibility) of any of the above conditions, they will be included for study by <sup>131</sup>I-miBG scintigraphy.

Progress: The principal investigator has PCS'd from BAMC as has the associate investigator. The exact status of this study is unknown.

# Detail Summary Sheet

Date: 25 Oct 94	Protocol Number: C-108-89	Status: Ongoing
Title: Evaluation of Interstitial Lymphoscintigraphy with Radioactive Technetium-Antimony Trisulfide Colloid (99m Tc-Sb <sub>2</sub> S <sub>3</sub> for Lymphedema, Internal Mammary and Excised Malignant Melanoma Lymphoscintigraphy)		
Start date: 8 Sep 89	Estimated completion date:	
Principal Investigator: James D. Heironimus, Lt COL, USAF, MC	Facility: Brooke Army Medical Center, Texas	
Department/Service: Department of Radiology	Associate Investigator(s): Neil Katz, MAJ, MC	
Key Words:		
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:	
Number of subjects enrolled during reporting period: <u>1</u>		
Total number of subjects enrolled to date: <u>9</u>		
Periodic review date: <u>16 Sep 92</u> Review results: <u>Continue</u>		

Objective(s): To determine the effectiveness of radioactive Tc99m Antimony Trisulfide Colloid in imaging lymph nodes.

Technical Approach: Patients will be selected and referred to Nuclear Medicine Service primarily by the Surgery and Oncology Clinic. For evaluation for lymphedema, intradermal injections of the radiopharmaceutical will be made in the distal extremities of interest. To evaluate the lymph drainage paths of a dermal region, injections will be made intradermally immediately adjacent to the site of the skin lesion/biopsy site. For all studies, scintigraphic imaging will be performed using an Anger Gamma Camera system. Multiple use of the appropriate areas will be attained immediately following the injection of the radiopharmaceutical as well as approximately 1-4 hours after injection. Body outlining and/or flood field imaging techniques will be performed to provide additional positional information.

Progress: The exact status of this study is unknown. Principal investigator has PCS'd and a new principal investigator has not been assigned.

# Detail Summary Sheet

Date: 7 Nov 94      Protocol Number: C-93-85      Status: Ongoing

Title: Efficacy of the Lateral Chest Radiograph on Computed Radiography Systems

Start date: Jul 93	Estimated completion date: Jul 94
Principal Investigator: Timothy J. Cramer, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Radiology	Associate Investigator(s): Anna K. Chacko, M.D. Joseph P. Spirnak, M.D. Raoul O. Hagen, M.D. Al Gest, M.D. James M. Lamiell, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To assess the efficacy of the lateral chest radiograph on routine outpatients using computed radiography systems.

Technical Approach: This is a prospective study of 3000 PA and Lateral chest radiographs obtained on the CR system. Patients will be from the Emergency Dept and Acute Care Clinic. No patients will be excluded.

Progress: We encountered difficulty with films. The study has been restarted and is currently in progress.



# Detail Summary Sheet

Date: 1 Dec 94      Protocol Number: C-94-47      Status: Ongoing

Title: A Prospective Evaluation of Technetium 99<sup>m</sup> Sestamibi in The Detection of Breast Cancer

Start date: 1 Jan 94	Estimated completion date: 31 Dec 94
Principal Investigator: Gilberto Sostre, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Radiology/Nuc Med Svc	Associate Investigator(s): Rashmikan Shah, M.D. Neil Katz, M.D. John Thomas, BCNP Vimal Sodhi, M.D. Johnny D. Alvarez, M.D.
Key Words: Technetium 99 <sup>m</sup> , Sestamibi, validate, establish, sensitivity, specificity	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 0

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): The use of Tc<sup>99m</sup> Sestamibi in this study would attempt to validate and establish the sensitivity and specificity of Tc<sup>99m</sup> Sestamibi in detecting breast cancers. This technique would be based on the increased biological differential uptake of breast cancer cells compared to normal breast cells.

Technical Approach: It is planned to carry out this open design study in two phases comparing Tc<sup>99m</sup> Sestamibi uptake in patients who are initially referred for a breast lump to mammography utilizing the abnormal breast biopsy as the gold standard for malignancy. If Tc<sup>99m</sup>Sestamibi's specificity and sensitivity are proven in discrete, palpable lesions for breast carcinoma malignancy, the second phase would add Tc<sup>99m</sup>Sestamibi scintigraphy to patients undergoing mammography who are found to have diffuse, fibrocystic breast disease or questionable mammograms without palpable lesions who are referred for a diagnostic breast biopsy.

Progress: Awaiting funding approval from the Jackson Foundation before starting study. Anticipate enrolling patients in mid January 1995.

# Detail Summary Sheet

Date: 27 Oct 94 Protocol Number: C-79-88 Status: Ongoing

Title: Collaborative Ocular Melanoma Study.

Start date: 8 Sep 88	Estimated completion date: 1998
Principal Investigator: Donald A. Hollsten, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Surgery/Ophthalmology	Associate Investigator(s): William L. White, MAJ, MC
Key Words: Melanoma	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
Total number of subjects enrolled to date: 2  
Periodic review date: 16 Sep 91 Review results: Continue

Objective(s): 1) To determine the efficacy of enucleation versus plaque irradiation in the treatment of medium size ocular melanomas.

2) To determine the efficacy of enucleation without pre-operative external radiation versus enucleation combined with pre-operative external radiation in the treatment of large ocular melanomas.

3) To determine the clinical course and community treatment standards in the treatment of small ocular melanomas.

Technical Approach: Unchanged. Collaborative Ocular Melanoma Study is designed to determine the most effective way to treat choroidal melanomas. Patients are divided into small tumors, medium tumors and large tumors based on diameter and thickness of the melanoma. Individuals in the small category are observed while individuals in the medium category are randomly divided into two treatment groups. One group was enucleated and the second will have radiation plaque therapy applied to the melanoma. Individuals in the large melanoma group are divided into either enucleation with preoperative radiation or enucleation without preoperative radiation.

Progress: One patient currently remains on study. Study is ongoing for patient accrual.

C-79-88 (continued)

around the country and our role will not be to collate, digest and evaluate the data but rather to provide patients to the central study authority at Johns

Hopkins University so that the appropriate number of cases can be entered into the study to achieve meaningful results. The first patient who was enrolled through Brooke Army Medical Center into the Collaborative Ocular Melanoma study has died from metastatic disease to his liver.

# Detail Summary Sheet

Date: 2 Sep 94                      Protocol Number: C-115-89                      Status: Ongoing

Title: Treatment of Metastatic Renal Cell Carcinoma with Cimetidine: A Phase II Trial. --

Start date: 8 Sep 89	Estimated completion date:
Principal Investigator: Ian M. Thompson, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Surgery/Urology	Associate Investigator(s): Arlene J. Zaloznik, LTC, MC M. Ernest Marshall, M.D.
Key Words:	
Accumulative MEDCASE Cost:	Estimated Accumulative OMA Cost:

Number of subjects enrolled during reporting period: 1  
Total number of subjects enrolled to date: 4  
Periodic review date: 16 Sep 91      Review results: Continue

Objective(s): 1) To evaluate the likelihood of response in order to assess whether this regimen should be advanced to further studies.

2) To evaluate and qualitative and quantitative toxicities of this regimen administered in a phase II study.

Technical Approach: All patients will receive cimetidine, 400 mg orally four times daily. There will be no dose reduction or escalation within this trial. Patients experiencing significant CNS toxicity will be removed from study. Any other toxicities requiring cessation of therapy will be documented.

Progress: There has been no change. The protocol remains open.

# Detail Summary Sheet

Date: 25 Oct 94 Protocol Number: C-61-90 Status: Ongoing  
 Title: Swimming and Myringotomy Tubes.

Start date: 12 May 90	Estimated completion date:
Principal Investigator: Kweon I. Stambaugh, LTC, MC	Facility: Brooke Army Medical Center
Department/Service: Department Surgery/Otorhinolaryngology	Associate Investigator(s): Jeffrey Braaten, CPT, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:
Number of subjects enrolled during reporting period: 100	
Total number of subjects enrolled to date: 160	
Periodic review date: Oct 92 Review results: Continue	

Objective(s): To determine the incidence of ear infection while swimming with middle ear ventilation tubes.

Technical Approach: All patients undergoing myringotomy and insertion of ventilation tubes that are intact and patent during the swimming season, June thru September, will be included in the study. Swimmers and non-swimmers will be randomized by a table of random numbers. A variety of ventilation tubes will be placed based on the surgeons personal preference. Patients will be seen routinely two weeks postoperatively and then every three months thereafter until the tubes are extruded. Patients will be given a calendar and questionnaire. The days swimming, the number of ear infections, and their relationship to an upper respiratory infection will be recorded.

Progress: Both the Principal and Associate Investigators have PCS'd from BAMC. This study is on hold pending assignment of a new investigator.

# Detail Summary Sheet

Date: 15 Sep 94 Protocol Number: C-91-90 Status: Ongoing

Title: The Incidence of Prostatism in Older Males Presenting for Herniorrhaphy.

Start date: 30 Aug 90	Estimated completion date:
Principal Investigator: Kevin Shandera, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Urology	Associate Investigator(s): Ian M. Thompson, MAJ, MC
Key Words: Prostatism Urine flow Rate	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 78

Total number of subjects enrolled to date: 78

Periodic review date: Review results:

Objective(s): To determine the incidence of prostatism in males 40 years of age and older who present for herniorrhaphy.

Technical Approach: One hundred consecutive men scheduled for herniorrhaphy will undergo urodynamics evaluation in an attempt to detect asymptomatic or minimally symptomatic physiologically-significant bladder outlet obstruction secondary to prostatic hyperplasia. Should such obstruction be encountered, Urology consultation would be requested before herniorrhaphy is undertaken.

Progress: Study has been completed. Data collection in process.

# Detail Summary Sheet

Date: 25 Oct 94                      Protocol Number: C-95-90                      Status: Ongoing

Title: Effect of the Use of Perioperative Antibiotics in the Incidence of Wound Infection Following Mastectomy.

Start date: 1 Aug 89	Estimated completion date:
Principal Investigator: Steven B. Olsen, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department Surgery/General Surgery	Associate Investigator(s): Daniel P. Otchy, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 31  
 Total number of subjects enrolled to date: 38  
 Periodic review date: \_\_\_\_\_ Review results: Continue

Objective(s): To prospectively analyze the effect of perioperative antibiotic use on the incidence of wound infection following mastectomy.

Technical Approach: This subject population will include all females who present to the General Surgery Service from August 1989 to December 1990. The subjects will be randomized to one of two double-blinded groups: the first group will received intravenous antibiotics in a standard perioperative regimen consisting of a dose preoperatively and postoperative doses for 24 hours postoperatively, and the second group will receive intravenous doses of saline at the same times when antibiotic would normally be administered. The incidence of wound infections and other infective complications will be monitored during the hospital stay and at follow-up visits.

Progress: Status is uncertain. Principal investigator PCS'd from BAMC prior to providing a progress report.

# Detail Summary Sheet

Date: 4 Sep 94                      Protocol Number: C-98-90                      Status: Ongoing

Title: An Open Label Extension Study Using Doxazosin Tablets for the Treatment of Benign Prostatic Hyperplasia in Patients with Mild to Moderate Essential Hypertension.

Start date: 7 Sep 90	Estimated completion date:
Principal Investigator: Ian M. Thompson, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Urology	Associate Investigator(s): Thomas A. Rozanski, M.D.C Leonard G. Renfer, MAJ, MC Douglas A. Schow, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 6 - 2 dropped  
Periodic review date: Nov 93                      Review results: Continue

Objective(s): 1) To determine the long-term safety and efficacy of doxazosin tablets in hypertensive patients with benign prostatic hyperplasia (BPH).  
2) To obtain information regarding the optimal dose of doxazosin tablets required on a long-term basis for patients with BPH.

Technical Approach: Patients who successfully complete the 16 week (double blind study may enter the open label extension study. They must do so within one week. Patients who withdrew from the 16 week study, after randomization, due to adverse experiences or lack of efficacy may also enter. The study is designated as an open-label, long-term, follow-up trial to the initial 16 week study. All patients in the open label trial will initially receive 1 mg of doxazosin daily and will be titrated upward at two week intervals, one dose level at a time, to a daily dose of 2, 4, 8, or 12 mg. A patient's upward titration will be dependent upon their adverse experiences, blood pressure response and BPH symptomatology. Once an optimal dose is achieved, it will be maintained unless the investigator determines that an adjustment in dose (lower or higher) is medically indicated.

Progress: During the past year, the same four patients remain on the study, all experiencing benefits of this agent. Patients with acceptable blood pressure and urinary symptoms with this agent will be kept at the dose achieved and periodically re-evaluated for patient satisfaction and blood pressure control. Enrollment closed. Ongoing for patient followup purposes.



# Detail Summary Sheet

Date: 25 Oct 94      Protocol Number: C-50-91      Status: Ongoing

Title: Comparison of Trigger Point Injections Using Kerolac Tromethamine versus Saline in the Treatment of Myofacial Pain Syndrome.

Start date: 2 May 91	Estimated completion date:
Principal Investigator: Roger L. Wesley, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Anesthesiology	Associate Investigator(s): William Strong, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 6  
 Total number of subjects enrolled to date: 6  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine if kerolac tromethamine is effective in providing pain relief in myofascial pain syndrome, and if so, for how long.

Technical Approach: Fifty adult volunteers who are referred to the pain clinic with myofascial pain syndrome will be enrolled in the double blinded, randomized study. Pain intensity and quality will be assessed using pressure algometry all visual analog pain scales. Patients will then be given trigger point injection with either ketorolac tromethamine or saline in a double blinded fashion. Pain reassessment will be done at 10 minutes, 6 hours, 1 day and 1 week following injection.

Progress: Principal investigator has separated from the Army. Currently there is no principal investigator to pursue this study. Data analysis is in progress.

# Detail Summary Sheet

Date: 15 Sep 94 Protocol Number: C-56-91 Status: Ongoing

Title: Urine Flow Rate Pre- and Post-Penile Prosthesis Implantation.

Start date: 4 Jun 91	Estimated completion date: 6/95
Principal Investigator: Kevin C. Shandera, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Urology	Associate Investigator(s): MAJ (P) Samuel Peretsman, M.D.
Key Words: Urine Flow Rate Penile Prosthesis	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 50

Total number of subjects enrolled to date: 50

Periodic review date: Review results:

Objective(s): To determine 1) those patients with bladder outlet obstruction secondary to benign prostatic hypertrophy prior to penile prosthesis implantation and 2) the incidence and degree of decreased urine flow rate secondary to penile prosthesis induced urethral obstruction.

Technical Approach: All patients scheduled for penile prosthesis implantation will complete a questionnaire and undergo pre- and postoperative urine flow rate utilizing the Dantec Uroflowmeter<sup>®</sup>.

Progress: Ongoing. Thus far, no significant difference in the urine flow rate has been observed following penile prosthesis.

# Detail Summary Sheet

Date: 1 Sep 94                      Protocol Number: C-73-91                      Status: Ongoing

Title: Does Magnesium Decrease the Incidence and Severity of Post-Cardiopulmonary Bypass Arrhythmias? A Double Blind, Randomized, Placebo Controlled Clinical Trial.

Start date: 30 Aug 91	Estimated completion date:
Principal Investigator: Paul D. Mongan, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Anesthesiology	Associate Investigator(s): Janet Hays, MAJ, MC Greg Bowman, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 0

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To determine the correlation of mononuclear blood cell (MBC) Mg concentrations with myocardial Mg concentrations.

2) To determine the correlation of myocardial and MBC Mg concentrations with post-CPB arrhythmias (ventricular and supraventricular).

3) To determine if MgSO<sub>4</sub> administration (30 mg/kg followed by 15 mg/kg/hour x 4 hours) is efficacious in reducing the incidence of post-CPB arrhythmias.

4) To determine the correlation of right atrial and left ventricular myocardial Mg concentration.

Technical Approach: Patients will be randomized to receive either 30 mg/kg MgSO<sub>4</sub> or placebo (normal saline) during CPB followed by 15 mg/kg/hour or placebo for four hours. The right atrial appendage (200 mg) will be sampled for intracellular Mg concentration. A left ventricular myocardial sample (200 mg) will be obtained if the left ventricle is to be incised for valve repair or aneurysmectomy. Myocardial samples will be obtained prior to the administration of the study medication. The detection method for arrhythmias will be a continuous Holter monitoring (leads CM5 and II) both pre- and

C-73-91 (continued)

post-CPB.

Progress: We are still awaiting laboratory support for the magnesium levels from Department of Clinical Investigation.

# Detail Summary Sheet

Date: 1 Sep 94

Protocol Number: C-74-91

Status: Ongoing

Neoadjuvant Hormonal Therapy Prior to Radical Prostatectomy for Clinical Stage A and B Carcinoma of the Prostate (RENAMED) Randomized Prospective Study Comparing Radical Prostatectomy Alone versus Radical Prostatectomy Preceded by Androgen Blockade in Clinical B2 Prostate Cancer

Start date: 26 Oct 92	Estimated completion date:
Principal Investigator: LTC Ian Thompson, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Urology	Associate Investigator(s): Thomas a. Rozanski, M.D. Leonard G. Renfer, M.D. Douglas A. Schow, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 8  
 Total number of subjects enrolled to date: 8  
 Periodic review date: 14 Sep 94 Review results: \_\_\_\_\_

Objective(s): To evaluate the safety and efficacy of a combination of Lupron Depot 7.5 mg (leuprolide acetate for depot suspension) and Eulexin (flutamide) prior to radical prostatectomy in clinical stage B2 prostatic cancer as compared to no therapy before radical prostatectomy.

Technical Approach: Ten patients with clinical stage B2 carcinoma of the prostate were randomized to receive either radical prostatectomy or adjuvant hormonal therapy. Patients eligible for the study must have had a negative staging evaluation including normal bone scan and no evidence of extraprostatic disease.

Progress: Study enrollment is complete. The patients remaining on study (one was lost to follow-up) are seen every 6 months and monitored for disease progression or recurrence. It is anticipated that the study results will be presented in April 1995 at the AUA meeting.

# Detail Summary Sheet

Date: 24 Oct 94                      Protocol Number: C-76-91                      Status: Ongoing

Title: Efficacy of Steroid in Reducing Post-Tonsillectomy Morbidity.

Start date: 30 Aug 91	Estimated completion date:
Principal Investigator: James Lee, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Otolaryngology	Associate Investigator(s): Sylvester G. Ramirez, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 18  
 Total number of subjects enrolled to date: 65  
 Periodic review date: 24 Oct 94      Review results: \_\_\_\_\_

Objective(s): To determine whether the use of intravenous perioperative steroids (dexamethasone) enhances the overall recovery in patients undergoing tonsillectomy: (1) by reducing postoperative pain, 2) by reducing postoperative swelling, and/or 3) allowing improved oral intake.

Technical Approach: The study group will include approximately 50 study subject and 50 controls. This study will compare post-tonsillectomy 1) pain, 2) tolerance of diet, i.e., liquids vs soft vs regular, 3) swelling, 4) temperature 5) weight fluctuation and 6) complications between patients receiving dexamethasone or placebo perioperatively.

Progress: Sixty-five patients have been entered but 100 is required for data analysis. Study is ongoing for patient accrual and data analysis.

# Detail Summary Sheet

Date: 15 Aug 94      Protocol Number: C-90-91      Status: Ongoing

Title: Phase I Protocol for the Evaluation of Active Immunization Against LHRH in Patients with Metastatic Cancer of the Prostate.

Start date: 7 Oct 91	Estimated completion date:
Principal Investigator: Ian M. Thompson, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Urology/Surgery	Associate Investigator(s): Peter Ravdin, MC Edward J. Mueller, LTC, MC Eric J. Zeidman, LTC, MC Paul Desmond, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4

Total number of subjects enrolled to date: 4

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To determine whether active immunization with a luteinizing hormone releasing hormone (LHRH) based vaccine will result in a significant immune response to LHRH in patients with metastatic prostatic cancer.

2) To determine if immunization against LHRH will cause suppression of luteinizing hormone (LH) and follicle stimulating hormone (FSH) levels in these patients.

3) To observe patients for signs of adverse effects following immunization.

Technical Approach: Four patients from BAMC will be referred on the study. The LHRH vaccine will be administered by Dr. Ravdin at the University of Texas Health Science Center on three occasions at two week intervals. Patients will return to BAMC for follow-up at monthly intervals for the first six months and then every three months for up to two years.

Progress: This study is closed to further accrual. Follow-p on all four patients continues.

# Detail Summary Sheet

Date: 1 Oct 94                      Protocol Number: C-91-92                      Status: Ongoing

Title: Does Preoperative Axillary Ultrasound and Tumor DNA Content Predict Axillary Lymph Node Metastases in Breast Cancer Patients with Clinically Negative Axilla.

Start date: 7 Oct 91	Estimated completion date:
Principal Investigator: Frank M. Robertson, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/SICU	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To prospectively analyze a group of variables to include age, size of primary tumor, receptor status, presence of adenopathy on axillary ultrasound, ploidy status and percent s-phase in breast cancer patients with clinically negative axilla.

Technical Approach: Data to include age, primary tumor size, estrogen receptor status, progesterone receptor status, axillary ultrasound, ploidy status, s-phase fraction, and final anatomic pathology results will be collected on all patients treated for breast cancer at BAMC for a period of 18 to 24 months. In patients with suggestive physical exams or mammograms, the ultrasound will be obtained prior to any surgical intervention such as biopsy.

Progress: Dr. Robertson has left and the protocol is on hold. No one on this service is currently involved in this project.



# Detail Summary Sheet

Date: 1 Sep 94                      Protocol Number: C-92-26                      Status: Ongoing

Title: Determination of Vecuronium Bromide Requirements in Nonthermally Injured Patients

Start date:	Estimated completion date:
Principal Investigator: MAJ Paul D. Mongan, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anesthesiology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To determine the ED<sub>95</sub> of vecuronium bromide for train-of-four twitch height depression in the nonthermally injured patient. 2) To compare the ED<sub>95</sub> determined for these patients to that determined for thermally injured patients.

Technical Approach: Patients will be premedicated at the discretion of the anesthesiologist. After placement of monitors and preoxygenation, patients will be induced with sufentanil citrate and thiopental sodium or ketamine as indicated by the patient's condition.

Progress: There has been no progress in obtaining patients to complete the study.

# Detail Summary Sheet

Date: 25 Oct 94                      Protocol Number: C-92-35                      Status: Ongoing

Title: Use of a Foot Compression Pump in the Prevention of Deep Vein Thrombosis in Hip Fractures

Start date:	Estimated completion date:
Principal Investigator: CPT James P. Stannard, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Orthopaedics	Associate Investigator(s): CPT Robert Harris, MC CPT Brian Allgood, MC COL Allan Bucknell, MC
Key Words: DVT, Foot Pump Total Joint Arthroplasty	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 29  
 Total number of subjects enrolled to date: 40  
 Periodic review date: 13 Dec 93      Review results:

Objective(s): To determine the clinical usefulness of the AVI foot pump as prophylaxis for deep venous thrombosis associated with hip fractures in individuals greater than 40.

Technical Approach: All male and female patients greater than 40 years of age sustaining a femoral neck fracture of intertrochanteric fracture presenting to the BAMC Orthopaedic Surgery Service within 48 hours of injury and requiring operative intervention without a history of prior deep venous thrombosis, without concomitant lower extremity precluding the use of a foot pump, not on warfare in therapy for other medical problems, and not pregnant will be eligible for inclusion in the study.

Progress: Seventy-five patients enrolled on study but not enough for achievement of statistical signs.

# Detail Summary Sheet

Date: 25 Oct 94                      Protocol Number: C-92-45                      Status: Completed

Title: The Incidence of Sexual Dysfunction After Transurethral Prostate Surgery Using Rigiscan Penile Tumescence and Rigidity Device

Start date:	Estimated completion date:
Principal Investigator: Duane Cespedes, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Urology	Associate Investigator(s): Ian M. Thompson, LTC, MC Eric J. Zeidman, MAJ, MC Samuel Peretsman, MD Alvin L. Sago, COL, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine the qualitative and quantitative effect of transurethral surgery upon erectile potency as measured by both sexual function instruments (inventory/questionnaire) and by Rigiscan tumescence/rigidity monitoring.

Technical Approach: All patients will be asked to complete a standardized sexual function questionnaire. Rigiscan monitoring will be performed on all patients within two months prior to prostate surgery and again three months following surgery. If at the three-month interval, the patient is experiencing any medical or physical problem which might interfere with the Rigiscan interpretation, the Rigiscan testing will be postponed for a clinically-appropriate period.

Progress: Because of the significant reduction in number of TURP's, this study has been closed.

# Detail Summary Sheet

Date: 1 Sep 94

Protocol Number: C-92-47

Status: Ongoing

Title: Acute Normovolemic Hemodilution: Comparison of the Use of Mixed Venous Oxygen Saturation to a Standard Technique

Start date:	Estimated completion date:
Principal Investigator: CPT Paul D. Mongan, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anesthesiology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost: \$33,386.00

Number of subjects enrolled during reporting period: 6

Total number of subjects enrolled to date: 6

Periodic review date: Review results:

Objective(s): 1) To evaluate a standard technique of hemodilution with regard to cardiovascular changes and compare this information to the safe limits of hemodilution which we will establish. 2) To establish the limits of safety of this technique based on recognized physiologic parameters by using mixed venous oxygen saturation as a guide to limit the amount of blood removed and to guide the need for transfusion therapy.

Technical Approach: Written informed consent will be obtained from the parents of 20 healthy patients scheduled for major spine surgery. A routine preoperative assessment will be performed by the anesthesia team and preoperative laboratory tests will be obtained. All patients will have anesthesia induced via mask with oxygen, nitrous oxide and halothane or with the intravenous agent thiopental. Intubation will be facilitated by the use of vecuronium bromide at a dose of 0.1 mg/kg.

Progress: Data has been completed and manuscript nearly completed. A finished copy will be forwarded when complete.

# Detail Summary Sheet

Date: 15 Aug 94                      Protocol Number: C-92-57                      Status: Ongoing

Title: Prostatic Intraepithelial Neoplasia as a Predictor of Subsequent Development of Carcinoma of the Prostate.

Start date:	Estimated completion date:
Principal Investigator: Ian M. Thompson, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Urology	Associate Investigator(s): COL Moo Cho, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine the association of PIN and AAH with subsequent development of CAP in men with benign prostatic hyperplasia (BPH).

Technical Approach: The slides of the pathologic evaluation of the benign glands in the 333 men who underwent TURP for BPH between 1980 and 1983 will be recovered. The slides will then be forwarded to Dr. Michael Braver at the University of Washington for evaluation. The evaluation will be made in a 'blinded' manner - i.e., Dr. Braver will not be aware of which patients subsequently developed carcinoma of the prostate.

Progress: Same status. This study still has yet to be activated. We are currently awaiting support from the VA Cooperative Trials group for pathologic processing.

# Detail Summary Sheet

Date: 1 Oct 94 Protocol Number: C-92-60 Status: Completed

Title: A comparison of intraoperative patient controlled sedation with sedation provided by an anesthesiologist for surgery performed under regional anesthesia.

Start date: Mar 92	Estimated completion date: Jun 93
Principal Investigator: John C. Talbot, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Anesthesiology	Associate Investigator(s): Joseph P. Ducey, LTC, MC
Key Words:	
Cumulative MEDCASE cost: 0	Estimated cumulative OMA cost: 0

Number of subjects enrolled during reporting period: 38

Total number of subjects enrolled to date: 38

Periodic review date: Review results:

Objective(s): To compare intraoperative patient controlled sedation administered on demand by a PCA infuser, with sedation provided by an anesthesiologist during regional anesthesia. The study will evaluate the feasibility of patient controlled sedation, patient and physician acceptance of this method, as well as patient benefits and adverse effects.

Technical Approach: Forty (40) ASA I and II adult patients (ages 18-70) scheduled for elective surgery under spinal or regional anesthesia will be investigated. Patients will be randomized into two groups. No pre-op sedations, hypnotics or opioids will be given. Routine monitors will be applied (continuous ECG, pulse oximetry, automated oscillometric blood pressure, nasal CO<sub>2</sub> and precordial stethoscope), and patients will be placed on 3 liters per minute oxygen by nasal prongs. Patients in groups one and two will receive a bolus of 0.5mg/kg of propofol over 2 minutes before performing the regional anesthetic.

Progress: This study has been completed. Data analysis currently in process.

# Detail Summary Sheet

Date: 27 Oct 94                      Protocol Number: C-92-66                      Status: Ongoing

Title: Impact of Dietary Manipulation on Prostate Cancer

Start date:	Estimated completion date:
Principal Investigator: Ian M. Thompson, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Urology	Associate Investigator(s): Barbi Helfrick, RN Susan Wise Wilson, MS, RD, LD Forrest Newman, LTC, MC Jean M. Johnson, Ph.D., RN
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To determine if a low fat, high fiber diet reduces serum prostatic specific antigen (PSA) in patients with carcinoma of the prostate. 2) To assess the impact of a low fat, high fiber diet on a patient's quality of life. 3) To assess the relationship between health beliefs, self-efficacy, social support and compliance with a low fat, high fiber diet.

Technical Approach: Pilot study will describe the impact of dietary manipulation on serum PSA, the factors which may contribute to dietary compliance, and the overall effect on quality of life. Subjects will be their own controls. The study group will consist of thirty men with known carcinoma of the prostate identified through the Urology Service Tumor Registry and who have (1) stable disease, (2) intact hormonal axis, and (3) elevated PSA (greater than 4 ng/ml as measured by the Hybritech assay). All men will be informed as to the nature of the study and will sign informed consent.

Progress: Currently there are 16 patients enrolled. Nine patients have completed the entire series.

# Detail Summary Sheet

Date: 15 Aug 94 Protocol Number: C-92-67 Status: Completed

Title: Pilot Study of Intravesical Bacillus Calmette-Guerrin (BCG) Therapy for Refractory Interstitial Cystitis.

Start date: 30 Jul 91	Estimated completion date:
Principal Investigator: Eric J. Zeidman, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Urology	Associate Investigator(s): Ian M. Thompson, MAJ, MC Edward J. Mueller, LTC, MC Paul M. Desmond, MAJ, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 5

Total number of subjects enrolled to date: 5

Periodic review date: Review results:

Objective(s): To determine if intravesical Bacillus Calmette-Guerrin therapy results in an improvement in interstitial cystitis pathologic signs and symptoms.

Technical Approach: Ten patients (in stages of five) with refractory interstitial cOystitis will be given six weekly intravesical treatments with one vial of Bacillus Calmette-Guerrin (BCG) vaccine. Patients will undergo cystoscopy under anesthesia before entrance into the study to ensure documented glomerulations upon second fill and biopsy proven absence of carcinoma in situ. Symptoms questionnaires will be filled out by the patient prior to BCG therapy, and at 3,6, and 12 months following therapy. If after ten patients we find a significant response to this therapy, we will submit another protocol.

Progress: Study is now closed and Temple University plans to conduct multicenter randomized trials.



# Detail Summary Sheet

Date: 24 Oct 94                      Protocol Number: C-92-74                      Status: Ongoing

Title: A-Preliminary Study on Multiple Linear Regression Analysis of Apnea Indices as a Function of Cephalometric Measurements in Preoperative and Postoperative Patients

Start date:	Estimated completion date:
Principal Investigator: LTC Sylvester Ramirez, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Otolaryngology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): A preoperative cephalogram and polysomnogram will be obtained in adult patients and compared to published norms.

Technical Approach: As part of their evaluation at the sleep clinic at BAMC, patients undergo a workup consisting of a history and physical, spirometry, TFTs, ABGs, cephalometric analysis and polysomnography. This is a preliminary study and thirty patients will be chosen who have OSA by polysomnography and choose surgical therapy.

Progress: Study ongoing as part of sleep study protocol C-92-81. One data analysis has been submitted and data continues to be evaluated.

# Detail Summary Sheet

Date: 1 Sep 94                      Protocol Number: C-93-15                      Status: Completed

Title: Multicenter Efficacy and Tolerability Study Comparing PROSCAR<sup>R</sup> (finasteride) and Placebo in the Treatment of Symptomatic Benign Prostatic Hyperplasia

Start date: 8 Dec 92	Estimated completion date: Sep 94
Principal Investigator: Ian M. Thompson, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Urology	Associate Investigator(s): Leonard G. Renfer, M.D. Douglas A. Schow, M.D. Julius L. Teague, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 12  
 Total number of subjects enrolled to date: 12  
 Periodic review date: 8 Dec 93      Review results: \_\_\_\_\_

Objective(s): To determine whether or not men with moderate BPH symptoms will improve significantly while taking Proscar (finasteride)

Technical Approach: Men of primarily Afro-American and Hispanic descent with moderate BPH symptoms are placed on Proscar for a period of one year after screening for prostate cancer. 80% of patients are placed on drug, 20% on placebo. Patients are monitored at 3 month intervals for status of urinary symptoms and occurrence of adverse experiences.

Progress: During the past year, one additional patient was dropped at his request due to side effects of the medication. Nine patients completed the required year of study, and the study was closed 31 August, 1994. Unblinding of the study drug and data analysis will be compiled by the statistical center for the study.

# Detail Summary Sheet

Date: 15 Aug 94	Protocol Number: C-93-23	Status: Ongoing
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Title: Phase III Trial of Coumarin (1, 2, -Benzopyrone) in Patients with Clinically Localized Prostatic Carcinoma Treated by Radical Prostatectomy Found Pathologically to Have High Risk of Recurrence

Start date: Jan 93	Estimated completion date:
Principal Investigator: Ian M.Thompson, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Urology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period:	1
Total number of subjects enrolled to date:	1
Periodic review date:	Review results:

Objective(s): The objectives of this Phase III study of Coumarin (1,2-benzopyrone) in patients with carcinoma of the prostate treated by radical prostatectomy who are at high risk of recurrence are to:

1. Determine whether coumarin therapy prevents progression or delays time to progression compared to placebo.
2. Evaluate the qualitative and quantitative toxicities of coumarin administered for prolonged periods.

Technical Approach: The coumarin therapy including drug information details, eligibility criteria, descriptive factors, pretreatment evaluation and treatment plan are outlined in protocol.

Progress: Status remains the same. No further patients accrued.

# Detail Summary Sheet

Date: 18 Aug 94      Protocol Number: C-93-29      Status: Ongoing

Title: Heart Valve Allograft CryoLife Cardiovascular, Inc. Non-Primary Clinical Protocol

Start date: 19 Dec 92	Estimated completion date:
Principal Investigator: Greg Bowman, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Cardiothoracic Surgery	Associate Investigator(s): David J. Cohen, M.D.
Key Words:	
Cumulative MEDCASE cost: 0	Estimated cumulative OMA cost: \$25,000.00
Number of subjects enrolled during reporting period: 2	
Total number of subjects enrolled to date: 7	
Periodic review date: 08/18/94      Review results: ?	

Objective(s): To develop the safety and efficacy data for the cryopreserved heart valve allograft which will support FDA approval for the continued distribution of these heart valves as a replacement or a treatment for diseased, damaged, malformed, or malfunctioning aortic or pulmonary heart valves.

Technical Approach: Patient population, inclusion/exclusion criteria and further specifics are in protocol.

Progress: Since the last periodic review date, two additional patients have been enrolled in the study. Their procedures were performed without complications and the allografts are functioning well in short term followup. No problems related to the allografts have been identified in followup of any of the patients currently enrolled.

ADDENDUM: 25 Oct 94 - Dr Cohen reported that on 7 Oct 94, the US District Court for Northern District of Illinois accepted a settlement of the allograft heart valve litigation in which the FDA agreed to rescind its premarket approval requirements for allograft heart valves. As a result, allograft heart valves are no longer subject to the Investigational Device Exemption (IDE) requirements mandated on June 26, 1991 and enforced on November 30, 1992. This means that the valves are no longer considered to be investigational and that Institutional Review Board (IRB) approval, investigational informed consent and additional patient follow-up are no longer required.

# Detail Summary Sheet

Date: 24 Oct 94      Protocol Number: C-93-32      Status: Ongoing

Title: Evaluation of Gastroesophageal Reflux in Preterm Infants

Start date: 1 Jan 93	Estimated completion date:
Principal Investigator: Russell J. Otto, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Otolaryngology	Associate Investigator(s): Judith O'Connor, M.D. Howard Heiman, M.D. Deborah M. Burton, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:
Number of subjects enrolled during reporting period: _____	
Total number of subjects enrolled to date: _____	
Periodic review date: _____ Review results: _____	

Objective(s): To determine whether gastroesophageal reflux (GER) can be reliably evaluated in intubated premature neonates. Sequential cases will be considered for inclusion in the study. The study population will consist of mechanically ventilated infants approximately 25-36 weeks gestational age.

Technical Approach: The proposed study will prospectively examine premature neonates in the 25-36 week gestational age range who meet the inclusion criteria. Inclusion criteria are infants requiring mechanical ventilation and tolerating enteral feeding. Exclusion criteria are full term infants, infants with symptoms associated with GER, infants with craniofacial disorders, neuromuscular disorders, syndromes associated with GER, or processes that mimic GER such as food intolerance, malabsorption, renal or infectious problems. Further details covered in protocol.

Progress: No results available at this time. Principal investigator has PCS'd from BAMC and protocol has not been assigned to another PI. Study remains ongoing.

# Detail Summary Sheet

Date: 1 Sep 94      Protocol Number: C-93-42      Status: Ongoing

Title: A Comparison of Six Different Intraoperative Site Determinations of Body Temperature Compared to Core Blood Temperature

Start date: 24 Dec 93	Estimated completion date:
Principal Investigator: Scott T. Davis, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anesthesiology & Operative	Associate Investigator(s): Richard B. Hecker, M.D. Bernard J. Rubal, Ph.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 25  
 Total number of subjects enrolled to date: 10  
 Periodic review date: Review results:

Objective(s): Patients undergoing surgical procedures are at risk for thermal perturbations. Most patients become hypothermic during surgery, although a few become hyperthermic. Temperature changes in either direction can be a cause of complications requiring treatment. The best technique for accurate measurement of intraoperative temperature remains a point of controversy. The objective of this study is to compare seven methods for noninvasive monitoring of body temperature: Tympanic, esophageal, oral, bladder, nasopharyngeal, rectal and forehead skin temperatures against core blood temperature as measured from the pulmonary artery.

Technical Approach: This study will compare the accuracy and precision of seven methods for monitoring body temperature in the operating room. Tympanic temperatures will be recorded utilizing an infrared sensitive electronic tympanic probe. Esophageal temperatures will be measured using an esophageal stethoscope/temperature probe placed in the distal esophagus. Further specifics outlined in protocol.

Progress: Data from 15 patients showed PA temperatures cooler than shell temperatures. Six point (33-38°C) calibration of 67 PA catheters performed in ISR Lab 8-94. Will continue with human subjects. Expect to complete project in 1995.

# Detail Summary Sheet

Date: 15 Aug 94      Protocol Number: C-93-46      Status: Completed

Title: Serum Prostate Specific Antigen (PSA) Levels Before and After Vasectomy

Start date: 18 Feb 93	Estimated completion date:
Principal Investigator: Ian M. Thompson, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Urology	Associate Investigator(s): Julius Teague, M.D. Cathy Pollard, R.N. Barbi Helfrick, R.N.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: 25  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine the relationship between serum PSA levels and vasectomy.

Technical Approach: The BAMC Urology Clinic presently does 12-15 vasectomies per month for elective permanent sterility. There is a mandatory group briefing for patients and their partners prior to the procedure. Fifty patients who volunteer at these briefings will be asked to have blood drawn for determination of PSA before, one week after, one month after, and six months after bilateral vasectomy for permanent surgical sterility. Patients who've had prior vasectomy will be excluded. Patients will be their own controls and the data analysis will be performed using students T test. The study group of 50 patients is reasonably sized and data accrual time will be prompt. Should trends in data suggest significant differences in PSA before and after vasectomy, the study could be extended to accrue larger more significant study population.

Progress: This study is now closed. The manuscript has tentatively been accepted by JAMA.

# Detail Summary Sheet

Date: 20 Oct 94      Protocol Number: C-93-48      Status: Ongoing

Title: Clinical Evaluation of Left Ventricular Assist Device

Start date: 12 Mar 93	Estimated completion date:
Principal Investigator: David J. Cohen, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Cardiothoracic Surgery	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): This study is designed to evaluate the use of a Pierce-Donachy Paracorporeal Ventricular Assist Device for patients with one of three problems: 1) post open heart surgery cardiac failure, 2) post myocardial infarction cardiogenic shock, and 3) cardiomyopathy when patients are awaiting heart transplantation and no donor hearts are available. This device is intended for use in patients with heart failure who would otherwise be unable to be supported through conventional medical means. The device would be used for a relatively short period (two to ten days) until either cardiac function returns to a level sufficient to allow for device removal or, in the case of "bridge to transplant," until a donor heart is available. If approval of this project is obtained, we hope to be named an investigational site by the Thoratec Corporation under agreement with the Food and Drug Administration.

Technical Approach: Outlined in protocol.

Progress: Protocol has not been activated. We still await funding.



# Detail Summary Sheet

Date: 24 Oct 94      Protocol Number: C-93-51      Status: Ongoing

Title: Mandibular Reconstruction by Distraction Osteogenesis

Start date: 23 Mar 93	Estimated completion date:
Principal Investigator: Sylvester G. Ramirez, M.D.	Facility: Wilford Hall AFMC Brooke Army Medical Center, Texas
Department/Service: Surgery/Otolaryngology	Associate Investigator(s): Peter D. Costantino, M.D. USAF
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1. Reconstruct segmental mandibular defects in selected human subjects by applying distraction osteogenesis; and 2. Critically evaluate the efficacy of distraction osteogenesis for mandibular reconstruction in humans as compared to standard techniques.

Technical Approach: Methods, significance, risk/benefit ratio, and other specifics outlined in protocol.

Progress: To date no patients have been entered at BAMC. Study remains ongoing for patient accrual.

# Detail Summary Sheet

Date: 1 Sep 94 Protocol Number: C-93-68 Status: Ongoing

Title: Intraincisional Bupivacaine and Intramuscular Ketorolac for Post-operative Pain Relief After Laparoscopic Bilateral Tubal Electrofulguration

Start date: 25 Mar 93	Estimated completion date:
Principal Investigator: Christina L. Szigeti, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anesthesiology	Associate Investigator(s): Julius Szigeti, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 60  
 Total number of subjects enrolled to date: 75  
 Periodic review date: Review results:

Objective(s): To compare the post-operative pain relief after operative laparoscopy and bilateral tubal electrofulguration (BTF) using intramuscular (IM) ketorolac alone, ketorolac with intraincisional bupivacaine and intraincisional bupivacaine alone. The total number of patients studied will be 128 (32 in each of the above groups plus a control group who will receive no study drugs). All patients will be American Society of Anesthesiologists (ASA) physical status I or II.

Technical Approach: Details including anesthesia, laparoscopic technique, pain evaluation and statistical analysis are outlined in protocol.

Progress: We are still enrolling patients. Data collection continues.

# Detail Summary Sheet

Date: 15 Aug 94      Protocol Number: C-93-76      Status: Ongoing

Title: Phase I/II Protocol for the Evaluation of Active Immunization Against LHRH in Patients with Cancer of the Prostate

Start date: 13 May 93	Estimated completion date:
Principal Investigator: Ian Thompson, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Urology	Associate Investigator(s): Peter Ravdin, M.D., UTHSCSA
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:
Number of subjects enrolled during reporting period: <u>1</u>	
Total number of subjects enrolled to date: <u>1</u>	
Periodic review date: _____ Review results: _____	

Objective(s): To determine whether active immunization with a luteinizing hormone releasing hormone (LHRH) based vaccine will result in a significant immune response to LHRH in patients with metastatic prostatic cancer, and to compare the effects of 2 immunization schedules. To determine if immunization against LHRH will cause suppression of luteinizing hormone (LHL) and follicle stimulating hormone (FSH) levels in men who have castrate testosterone levels, and cause a decrease in testosterone levels in men who have not undergone orchiectomy. To observe patients for signs of adverse effects following immunization.

Technical Approach: Protocol covers all specifics. It should be noted that all laboratory specimens will be obtained and assayed at UTHSCSA and no assays will be performed at BAMC. All immunizations will be performed at UTHSCSA. Additionally, it must be noted that although a total of 30 patients will be accrued to this protocol, this number is a total of both participating institutions.

Progress: One patient is now receiving immunizations and a second entered the study on 3 Aug 94.

# Detail Summary Sheet

Date: 1 Sep 94                      Protocol Number: C-93-78                      Status: Ongoing

Title: The Use of EEG and Hemodynamic Parameters in the Design of Intelligent Anesthetic-Control Systems

Start date: 14 May 93	Estimated completion date:
Principal Investigator: Douglas Anderson, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anesthesiology & Op	Associate Investigator(s): Paul Mongan, M.D. John Ward, Ph.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2  
 Total number of subjects enrolled to date: 2  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): This study will collect hemodynamic and physiologic data in conjunction with raw EEG and Auditory evoked Responses from patients undergoing general anesthesia for surgical procedures. This data will be analyzed off-line for correlations of EEG changes with hemodynamic changes that are interpreted clinically as changes in anesthetic depth. Utilizing this information, signal processing techniques, adaptive control theory and artificial intelligence concepts will be applied to develop a anesthesiologist in providing patient care.

Technical Approach: This study is descriptive in nature and seeks only to assemble a data base of patient data for future study and analysis.

Progress: There has been no progress in this study.

# Detail Summary Sheet

Date: 15 Sep 94      Protocol Number: C-93-93      Status: Ongoing

Title: Determination of Preoperative Intravascular Volume Deficit in Bowel-Prepped Surgical Patients

Start date: 1 Jul 93	Estimated completion date:
Principal Investigator: Todd D. Storch, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anesthesiology & Operative Svc	Associate Investigator(s): Joseph P. Ducey, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 20  
 Total number of subjects enrolled to date: 20  
 Periodic review date: 15 Sep 94      Review results: \_\_\_\_\_

Objective(s): To determine if oral bowel prep solutions as administered routinely prior to abdominal surgery, reduce intravascular volume in the adult surgical patient before surgery. Null hypothesis: Oral bowel preparation has no effect on preoperative intravascular volume status.

Technical Approach: 40 ASA physical status 1-3 patients, ages 18-65, presenting for elective surgical procedures will be enrolled in the study after written consent is obtained. Further specifics given in protocol.

Progress: No additional patients enrolled secondary to scholastic/professional demands (i.e., Boards) and concomitant difficulty with technique (difficult to reliably maintain butterfly in peripheral vein for both injection and withdrawal at timed intervals). No sampling difficulty encountered with protocol C 94-18 (via 4-line) but this study not approved for preop 4-line placement. No additional funding requirements anticipated for FY 95.

# Detail Summary Sheet

Date: 1 Sep 94                      Protocol Number: C-93-91                      Status: Ongoing

Title: Aeric and Particulate Microemboli as Etiologic Factors in the Development of Neurobehavioral Dysfunction Following Cardiopulmonary Bypass and Vascular Surgery: An Outcome Study.

Start date: 7 Oct 91	Estimated completion date:
Principal Investigator: Paul D. Mongan, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/ Anesthesiology	Associate Investigator(s): Maurice Albin, ND
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine the incidence of air and particulate emboli during cardiopulmonary bypass (CPB) using transcranial doppler ultrasound as a detection device and to detect, correlate, and follow postoperative neurologic and psychometric changes seen in patients.

Technical Approach: This is a multicenter outcome study with UTHSCSA and Wilford Hall Medical Center. 125 patients requiring CPB will be enrolled with 25 patients for peripheral vascular procedures not requiring CPB serving as controls. Psychologic testing and neurologic evaluation will be performed preoperatively, at discharge and at 6 weeks, 6 months and 1 year after discharge. Intraoperative noninvasive testing will consist of transcranial doppler ultrasound (TCD) for the detection of air and particulate emboli and EEG monitoring by a commercially available processed EEG monitor. Anesthetic regimens will be standardized.

Progress: We are still awaiting funding by NIH.

# Detail Summary Sheet

Date: 1 Sep 94      Protocol Number: C-93-113      Status: Ongoing

Title: Effects of Desflurane on the Amplitude and Latency Characteristics of Brainstem Auditory, Midlatency Auditory, Median and Posterior Tibial Nerve Evoked Potentials

Start date: Aug 93	Estimated completion date:
Principal Investigator: Paul D. Mongan, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anesthesiology & Operative Svc	Associate Investigator(s): Joseph P. Ducey, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 6  
 Total number of subjects enrolled to date: 8  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine the effect of desflurane on the amplitude and latency characteristics of multimodality sensory evoked potentials.

Technical Approach: Study design, population, methods and specifics covered in protocol.

Progress: We anticipate completion of this study by December 1994.

# Detail Summary Sheet

Date: 15 Aug 94      Protocol Number: C-93-120      Status: Ongoing

Title: Menstrual Cycle Impact Upon Breast Cancer - Women - Surgery Balance

Start date: Aug 93	Estimated completion date:
Principal Investigator: Johnny Alvarez, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/General Surgery	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): The prospective observational study described by this protocol will carefully document the menstrual cycle stage of breast cancer or benign breast biopsy and/or breast cancer resection and measure cellular and humoral activities known or suspected to affect metastatic potential in patient samples obtained before and following that biopsy and/or resection.

Technical Approach: Study design, treatment plan/flow, clinical evaluation/follow-up, and specifics outlined in protocol.

Progress: Awaiting final MRDC approval.



# Detail Summary Sheet

Date: 1 Dec 94      Protocol Number: C-94-01      Status: Ongoing

Title: Magnitude of Hypotension With and Without Intravenous Fluid Preload in Healthy Patients Receiving Subarachnoid Anesthesia

Start date: 1 Oct 94	Estimated completion date:
Principal Investigator: Christina Szigeti, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anesthesiology & Op Svc	Associate Investigator(s):
Key Words: Subarachnoid Anesthesiology Hypotension	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 39  
 Total number of subjects enrolled to date: 39  
 Periodic review date: Review results:

Objective(s): To compare the magnitude of hypotension in healthy patients undergoing subarachnoid anesthesia with and without a fluid preload. The total number of patients studied will be one hundred fifty.

Technical: It is hypothesized that there will be no difference in the magnitude of blood pressure drop with or without fluid preload in patients receiving SAB. One hundred and fifty patients will be enrolled to obtain statistical significance. Criteria for inclusion and other specifics are outlined in protocol.

Progress: Enrollment continuing.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-05                      Status: Ongoing

Title: Oral Atropine Premedication in Children: Effects on Airway and Respiratory Events During General Anesthesia for PE Tube Placement

Start date: Oct 93	Estimated completion date:
Principal Investigator: Christopher E. Swide, M.D.	Facility: Darnall ACH & Brooke Army Medical Center, Texas
Department/Service: Surgery/Anesthesiology & Op Svc	Associate Investigator(s): Hunter Richmond, M.D. Kim Cantees, M.D. Ken Azarow, M.D. James Redwine, CRNA
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 140  
 Total number of subjects enrolled to date: 140  
 Periodic review date: Review results:

Objective(s): Determine the effect of oral atropine premedication on reducing significant airway and respiratory events during the induction, maintenance, and recovery in children undergoing general anesthesia for PE tube placement.

Technical Approach: Study design including hypothesis, statistical analysis and details are included in protocol.

Progress: Continuing to evaluate.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-09                      Status: Ongoing

Title: The Incidence of Concomitant Leg and Foot Compartment Syndrome

Start date:	Estimated completion date:
Principal Investigator: James A. Dahl, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Orthopaedic Surgery	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 0  
Periodic review date: Review results:

Objective(s): To determine the incidence of foot compartment syndrome concurrent with leg compartment syndrome.

Technical Approach: The patients would be drawn from the population treated at BAMC and would consist of any patients presenting for evaluation and treatment of tibial fractures or suspected acute leg compartment syndrome. Specifics are given in protocol.

Progress: Haven't had anyone eligible during last year.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-13                      Status: Completed

Title: A Pilot Study of the Histologic Response To and Drug Distribution of the 5-FU-e-Implant (5011) Administered Prior to Prostatectomy in Patients with Stage B or C Prostatic Carcinoma

Start date: Nov 93	Estimated completion date:
Principal Investigator: Ian Thompson, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Urology	Associate Investigator(s): Julius L. Teague, M.D. Leonard Renfer, M.D. Douglas Schow, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 3  
 Total number of subjects enrolled to date: 3  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To evaluate the histologic response and intraprostatic drug distribution profile following administration of the 5-FU-e TI when administered prior to radical prostatectomy in patients with Stage B or C prostate carcinoma. To determine effective dose levels of the 5-FU-e TI and to investigate the potential antitumor effect for local disease control.

Technical Approach: Study design, conduct of study and detailed specifics are outlined in protocol.

Progress: This study is now closed to accrual. Pathologic evaluations are ongoing at the University of Colorado and results will be forthcoming.

# Detail Summary Sheet

Date: 1 Dec 94 Protocol Number: C-94-18 Status: Ongoing

Title: Determination of Perioperative Intravascular Volume Status in TURP Patients Under Subarachnoid Anesthesia

Start date: 16 Dec 93	Estimated completion date:
Principal Investigator: Todd D. Storch, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anes & Operative Svc	Associate Investigator(s): Brian Thwaites, M.D.
Key Words:	Douglas M. Anderson, M.D.
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine and qualify perioperative changes in intravascular volume status secondary to absorption of irrigation solution during TURP.  
 Null hypothesis: No detectable changes in perioperative intravascular volume occur during TURP.

Technical Approach: 50 ASA 1-3 patients, age 18-90 presenting for elective transurethral procedures under subarachnoid anesthesia will be enrolled. Group A will consist of 25 patients undergoing TURP; Group B will be a control group of similar number whose transurethral procedure does not involve prostatic resection. Resection of bladder tumors with irrigation will be deemed acceptable for Group B as substantial absorption of irrigation from bladder tissue has not been demonstrated.

Progress: Four patients enrolled to date but anticipate accelerated enrollment as Urology caseload increases. No preliminary conclusions thus far due to early point in study. No patient complications experienced thus far.

## Detail Summary Sheet

Date: 1 Dec 94

Protocol Number: C-94-20

**Status:** Ongoing

**Title: The Use of Urine Cytology for the Early Diagnosis of Transitional Cell Carcinoma of the Bladder in High Risk Patients**

Start date: Dec 93	Estimated completion date: Dec 94
Principal Investigator: Douglas A. Schow, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Urology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost: 0	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 18

Total number of subjects enrolled to date: 23

Periodic review date: Jun 94 Review results: See below

Objective(s): To determine the yield of urinary cytology in the early detection of bladder cancer.

**Technical Approach:** If the positive predictive value of voided urinary cytology should prove to detect patients with bladder cancer with high specificity, high risk groups (cigarette smokers, individuals with exposures to known urothelial carcinogens) may consider early detection to reduce mortality and morbidity from bladder cancer.

Progress: 1 patient: (+) hematuria, (-) urine cytologies  
IVP(-), cysta - local dysplasia by TURBT  
1 patient: (+) hematuria, (-) urine cytologies, (-) cystoscopy  
Mass on IVP - CT Scan - complete cyst - will be  
followed by renal U/S  
9 patients: (+) hematuria, (-) urine cytologies, (-) IVP, (-)  
cystoscopy  
7 patients: (-) U/A, (-) urine cytologies

# Detail Summary Sheet

Date: 1 Dec 94 Protocol Number: C-94-21 Status: Ongoing

Title: A Prospective Study Evaluating Optimal Volume of Blood Injected into the Epidural Space for Treatment of Post Dural Puncture Headache

Start date: Dec 93	Estimated completion date: 20 Sep 94
Principal Investigator: Marc Boin, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anesthesiology & Operative Svc	Associate Investigator(s): Sam Sayson, M.D.
Key Words: Anesthesia, Post dural puncture headache, regional anesthesia, complications	
Cumulative MEDCASE cost: -0-	Estimated cumulative OMA cost: -0-

Number of subjects enrolled during reporting period: 6  
Total number of subjects enrolled to date: 6  
Periodic review date: 20 Review results: No difference

Objective(s): To assess, in a prospective manner, the optimal volume of blood to be injected into the epidural space for relief of post dural puncture headaches. To compare the effects of using a predetermined volume of epidurally injected blood versus a volume of blood which is titrated to patient tolerance in the relief of PDPH.

Technical Approach: Null Hypothesis - There is no difference in failure rate of epidural blood patch for treatment of PDPH when a volume of 5, 10, 15cc of blood is used. Study population, data collection and statistical analysis included in protocol.

Progress: PI has left BAMC. Patient population with post dural puncture headaches has decreased. Study population is too small at this time to evaluate hypothesis.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-28                      Status: Ongoing

Title: Clinical Evaluation of Low Dose Heparin in Conjunction with a Heparin Coated Circuit for Cardiopulmonary Bypass

Start date: 11 Jan 94	Estimated completion date:
Principal Investigator: Greg Bowman, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Cardiothoracic Surgery	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To test the safety and efficacy of lower dose heparinization (100 units/kg) in conjunction with a covalently bonded heparin coated (DuraFlow™, Edwards Labs) cardiopulmonary bypass circuit in patients undergoing cardiac surgery.

Technical Approach: A randomized, prospective analysis of patients undergoing elective coronary artery bypass surgery. Blood samples will be drawn preoperatively, after heparinization but before bypass, at 30 minute intervals during bypass, and 30 minutes after protamine administration. These samples will measure ACT, fibrinopeptide A, platelet count, serum hemoglobin, and fibrinogen. Bleeding time, prothrombin time, partial thromboplastin time, and thrombin time will be measured preoperatively, and 30 minutes and 4 hours after protamine administration. Thromboelastography will be performed preoperatively and 30 minutes following protamine administration. Following surgery the bypass circuit will be examined for macroscopic clot and the patient's mediastinal drainage will be monitored for 24 hours. Requirements for transfusions of blood and blood products will be monitored for the 24 hr perioperative period. Patients will be dropped from the study if they require the intra-aortic balloon pump, or if bypass time exceeds 4 hours. Analysis of quantitative data, presented as the mean +/- standard deviation, will be accomplished with the Student t test.

Progress: Has yet to be activated. Pending approval and receipt of funds.



# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-31                      Status: Ongoing

Title: Headache After Spinal Anesthesia for Cesarean Section: A Comparison of the Quincke and Whitacre Spinal Needles and the Paramedian and Midline Approaches

Start date: 14 Jan 94	Estimated completion date:
Principal Investigator: Christina Szigeti, M.D.	Facility: DACH Brooke Army Medical Center, Texas
Department/Service: Surgery/Anesthesia & Operative Svc	Associate Investigator(s): Douglas M. Anderson, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: ?  
 Total number of subjects enrolled to date: ?  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To compare of the study is to compare the incidence of PDPH in pregnant patients receiving spinal anesthesia for cesarean section using two different spinal needles (Quincke and Whitacre) and two different approaches to the subarachnoid space (midline and paramedian). The total number of patients studied will be two hundred (fifty in each group).

Technical Approach: Hypothesize: 1. The paramedian aproach using the 25 gauge Quincke needle is associated with the same incidence of PDPH as the paramedian approach using the 25 gauge Whitacre needle. 2. The paramedian approach using the Quincke needle is associated with less PDPH than the midline Quincke method. 3. The paramedian approach using the quincke needle is associated with the same incidence of PDPH as the midline Whitacre method. Total number of subjects required for statistical significance is estimated to be 200.

Progress: Dr. Szigeti has transferred to Darnall ACH and the study will be basically done there.

# Detail Summary Sheet

Date: 1 Dec 94

Protocol Number: C-94-33

Status: Ongoing

Title: The Effect of Transexamic Acid When Given After Cardiopulmonary Bypass and Its Correlation with Thromboelastography

Start date: 21 Jan 94

Estimated completion date:

Principal Investigator:  
Ron Brannon, M.D.

Facility:  
Brooke Army Medical Center, Texas

Department/Service:  
Surgery/Anesthesiology & Operative Svc

Associate Investigator(s):

Key Words:

Cumulative MEDCASE cost:

Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_

Total number of subjects enrolled to date: \_\_\_\_\_

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): Will Transexamic Acid (TA) prove to be beneficial after cardiopulmonary bypass (CPB) routinely or in a subgroup of patients with an abnormal thromboelastography (TEG)?

Technical Approach: Patients will be ASA III-IV patients scheduled for elective nonemergency coronary bypass or valve operation with extracorporeal circulation. All patients will have normal preoperative coagulation profiles and be between the ages of 18 and 80. Exclusion criteria, transfusion criteria and data collection data included in protocol.

Progress: No data available.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-41                      Status: Ongoing

Title: Efficacy and Safety of Ciprofloxacin Ophthalmic Ointment Versus TOBREX Ophthalmic Ointment for Treating Bacterial Conjunctivitis in Children

Start date: 28 Jun 94	Estimated completion date:
Principal Investigator: Mary O'Hara, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Ophthalmology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Review results:

Objective(s): The objectives of this study are to compare clinical and bacterial efficacies and incidence of adverse reactions for topical Ciprofloxacin Ophthalmic Ointment against TOBREX in children (ages 2-12) with acute bacterial conjunctivitis. Acute is defined as having a duration of one week or less.

Technical Approach: Materials/methods, subjects, study procedure, statistical evaluation, etc., furnished in protocol.

Progress: Alcon has decided to pursue study at fewer medical centers. Therefore BAMC is an alternate site.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-46                      Status: Ongoing

Title: A Study of the Ability of Anesthesiologists and Surgeons to Differentiate Arterial from Central Venous Blood Samples by Visual Inspection of Hue

Start date: 8 Feb 94	Estimated completion date:
Principal Investigator: Christina Szigeti, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anes & Op	Associate Investigator(s): Van Garman, M.D. Paul D. Mongan, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): The purpose of this study is to determine whether it is possible for physicians familiar with central line placement are able to differentiate arterial from venous source by visual inspection of the blood in a syringe. The blood will be drawn from arterial lines and internal jugular vein catheters at four different fractional inspired oxygen concentrations to simulate those concentrations most frequently used in the operating rooms. They will be analyzed under low light and bright light conditions by anesthesiologists and surgeons.

Technical Approach: This is a descriptive study which will determine the positive predictive value of a visual inspection of hue to determine blood source. Ten patients who require arterial line and central venous catheter placement for their surgery will be enrolled and informed consent will be obtained. After intubation, each patient will be placed on four different FIO<sub>2</sub> (21%, 30%, 50% and 100% for 10 minutes and then a 1.5cc sample of arterial and central venous blood will be aspirated into a blood gas syringe. Further details in protocol.

Progress: None at this time.

# Detail Summary Sheet

Date: 1 Dec 94	Protocol Number: C-94-52	Status:
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Title: Incident of Post-dural Puncture Headaches with Continuous Spinal Anesthesia and 24 Gauge Catheter Over 26 Gauge Needle

Start date: 11 Feb 94	Estimated completion date:
Principal Investigator: R. Scott Brown, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Anes & Op Svc/Surgery	Associate Investigator(s): Philip J. Becker, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: _____
Total number of subjects enrolled to date: _____
Periodic review date: _____ Review results: _____

Objective(s): To evaluate the incidence of posdural puncture headache (PDPH) with the new Johnson-Bittner 26 gauge needle with which a 24 gauge catheter is passed over the top for continuous spinal anesthesia (CSA) in patients at high risk for PDPH (age 18-40).

Technical Approach: It has been proposed that incidences of PDPH with large bore catheters and needles and CSA is 70%. This study will theoretically lower this incidence by using a smaller needle (26 gauge) and tight fitting catheter (24 gauge) to reduce CSF leakage and will avoid complications of cauda equina syndrome by avoiding the use of a microcatheter, 5% lidocaine and any hyperbaric solutions. Patient evaluation, symptoms and specifics are outlined in protocol.

Progress: Study progressing well. There is no data to report at this time.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-54                      Status: Completed

Title: Quality of Life Issues Following Treatment for Localized Prostate Cancer

Start date: 1 Jan 94	Estimated completion date: Apr 94
Principal Investigator: Leonard Renfer, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Urology	Associate Investigator(s): Ian M. Thompson, M.D.
Key Words: Quality of life, prostate, cancer	
Cumulative MEDCASE cost: .00	Estimated cumulative OMA cost: \$50.00

Number of subjects enrolled during reporting period: 87  
 Total number of subjects enrolled to date: 87  
 Periodic review date: Apr 94                      Review results:

Objective(s): Assess how patients feel about their outcome following treatment for localized prostate cancer.

Technical Approach: Survey Data. A major review of the literature regarding efficacy and morbidity of observation, surgery, and radiation therapy suggested comparable result for the three options. Whether or not this is true, it is clear that future treatment decisions will require consideration of the patients' assessment of the treatment. These surveys will provide a means to elicit the patients' perspective.

Progress: Study completed. Results will be combined with several other medical centers for final tabulation, which is pending. To summarize results, both surgical and radiation therapy patients suffer impotence at a rate close to 70%, yet both groups are generally satisfied with approximately 85% choosing the same therapy again if given the choice.

# Detail Summary Sheet

Date: 1 Dec 94      Protocol Number: C-94-61      Status: Ongoing

Title: Peritoneal Irrigation in Gunshot Wounds of the Abdomen

Start date: 4 Mar 94	Estimated completion date: 30 Jun 95
Principal Investigator: John J. Kelemen, III, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Gen Surg	Associate Investigator(s): James Obney, M.D. R. Russell Martin, M.D.
Key Words:	
Cumulative MEDCASE cost: None	Estimated cumulative OMA cost: None

Number of subjects enrolled during reporting period: 12  
 Total number of subjects enrolled to date: 12  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To correlate cell count values for peritoneal irrigation with physical examination, peritoneal penetration and the extent of injury in gunshot wounds to the abdomen.

Technical Approach: Description of subjects and controls: All individuals brought to BAMC with a gunshot wound to the abdomen. Since the majority of patients with gunshot wounds to the abdomen have a visceral injury, it is estimated that a large number of subjects (200) will be required to generate a non-visceral injury group of sufficient size to attain statistical significance. Experimental design/methods: Exploration celiotomy is currently performed on all patients with gunshot wounds to the abdomen at BAMC. This practice will not be significantly changed or delayed. At the initiation of celiotomy, in stable patients, the abdomen will be lavaged with 1000cc of lactate ringer's solution and a cell count will be performed on the fluid return. The operating surgeons will be blinded from the results of lavage analysis during the operation. Data collection and statistical analysis outlined in protocol.

Progress: No adverse consequences. Initial results suggest DPL is an excellent discriminator.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-62                      Status: Ongoing

Title: The Effect of Intravenous Ketorolac on Platelet Function During General Anesthesia

Start date: 10 Mar 94	Estimated completion date: Sep 94
Principal Investigator: Brian K. Thwaites, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anesthesiology & Op Svc	Associate Investigator(s): Daren Nigus, M.D. Gregory W. Bouska, M.D. Paul Mongan, M.D. Gerald Merrill, Ph.D. Eleanor Ayala
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 28  
Total number of subjects enrolled to date: 28  
Periodic review date: Review results:

Objective(s): To determine whether ketorolac given intravenously has significant effects on platelet function during general anesthesia.

Technical Approach: Prior studies demonstrate inhibition of platelet function in awake volunteers in the form of prolonged bleeding times and diminished platelet aggregation studies. Other studies demonstrate that under general anesthesia, platelet function is enhanced and that the production of thromboxane B2 is enhanced. To date, the net effect of general anesthesia and IV ketorolac has not been studied.

Progress: Nearing completion.



# Detail Summary Sheet

Date: 1 Dec 94      Protocol Number: C-94-73      Status: Ongoing

Title: Sore Throat with the Laryngeal Mask Airway in Pediatric Patients - The Effect of Lubrication

Start date: 25 Mar 94	Estimated completion date: Mid 96
Principal Investigator: Tara L. Chronister, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anes & Op Svc	Associate Investigator(s): Samuel C. Sayson, M.D. Jason P. Fontenot, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine if the type of lubrication used on a laryngeal mask airway affects the incidence and severity of sore throat after endotracheal intubation with that of the laryngeal mask. After obtaining informed consent, eligible patients presenting for elective surgery will be randomized into four study groups: 1. Endotracheal intubation; 2. Laryngeal mask airway lubricated with normal saline; 3. Laryngeal mask airway lubricated with KY jelly; 4. Laryngeal mask airway lubricated with 2% lidocaine jelly.

Technical Approach: Hypotheses to be tested, technical validity of procedures, sample size, subjects, etc, included in protocol.

Progress: Number of pediatric patients meeting criteria is limited. Plan to have Arkansas Childrens Hospital cooperate with study to increase numbers.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-74                      Status: Ongoing

Title: Sore Throat with the Laryngeal Mask Airway - The Effect of Lubrication

Start date: 1 Apr 94	Estimated completion date: Dec 95
Principal Investigator: Tara L. Chronister, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anes & Op Svc	Associate Investigator(s): Samuel C. Sayson, M.D. Jason P. Fontenot, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: Approx 10

Total number of subjects enrolled to date: \_\_\_\_\_

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine if the type of lubrication used on a laryngeal mask airway affects the incidence and severity of sore throat after endotracheal intubation with that of the laryngeal mask. After obtaining informed consent, eligible patients presenting for elective surgery will be randomized into four study groups: 1. Endotracheal intubation; 2. Laryngeal mask airway lubricated with normal saline; 3. Laryngeal mask airway lubricated with KY jelly; 4. Laryngeal mask airway lubricated with 2% lidocaine jelly.

Technical Approach: Hypotheses to be tested, technical validity of procedures, sample size, subjects, etc, included in protocol.

Progress: Majority of eligible patients enrolled appear to be working well. Will continue to enroll patients.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-76                      Status: Ongoing

Title: Rocuronium onset of action: An EMG dose response study of the adductor pollicis, orbicularis oculi and the adductor muscles of the larynx

Start date: 28 Feb 94	Estimated completion date:
Principal Investigator: Paul Mongan, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anesthesiology & Op Svc	Associate Investigator(s): Sam Sayson, M.D. Scott Brown, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine the onset of action and depth of blockade at the adductor pollicis, orbicularis oculi and the muscles of the larynx. To determine the difference in onset of action and depth of blockade with 2X, 3X and 4X an ED95 dose of rocuronium bromide.

Technical Approach: Null hypothesis, technical validity of procedures, study design, inclusion/exclusion criteria included in protocol.

Progress: No progress.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-77                      Status: Ongoing

Title: Comparison of Apraclonidine (Iopidine) 1% and 0.5% in Intraocular Pressure Control After Argon Laser Trabeculoplasty in Patients with Primary Open Angle Glaucoma

Start date: 5 Apr 94	Estimated completion date: 30 Nov 94
Principal Investigator: David R. Rivera, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Ophthalmology	Associate Investigator(s): John A. Campagna, M.D. (Staff)
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 46  
 Total number of subjects enrolled to date: 46  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): The study purpose is to assess if apraclonidine (Iopidine) 0.5% will have the same or similar effect on accurate intraocular pressure changes after argon laser trabeculoplasty as the standard 1% apraclonidine.

Technical Approach: The hypothesis is that 0.5% apraclonidine will control IOP elevations as well as 1% after ALT surgery. To ascertain this, a double blind study is proposed in which primary open angle glaucoma (POAG) patients who have ALT will be invited to participate. A Coherent 920 tunable dye Argon laser is used with settings of 0.1 sec pulses and 50 micron spots of Argon green laser. Laser power is typically between 400 and 1000 milliwatts and titrated in each individual patient to obtain the desired effect of mild to blanching tissue at the photocoagulation site. Detailed specifics included in protocol.

Progress: To date there have been no adverse reactions to either concentration of apraclonidine. Both concentrations have presented intraocular pressure spikes. No patient has had an intraocular pressure spike above 10 mmHg.

# Detail Summary Sheet

Date: 1 Dec 94      Protocol Number: C-94-78      Status: Ongoing

Title: Survival and Morbidity Tradeoffs in Prostate Cancer Treatment - Impact of Patient Perspective

Start date: 28 Feb 94	Estimated completion date:
Principal Investigator: Ian M. Thompson, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Urology	Associate Investigator(s): Jean M. Johnson, PhD, RN Barbi Helfrick, BSN, RN Douglas Schow, M.D. Leonard Renfer, M.D. Julius L. Teague, M.D. John Ward, PhD
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To compare men with different prostate cancer conditions on their choice of treatment, factors which influence treatment choices, and perceptions about treatment risks and benefits. To examine the relationship between the maximum acceptable risk for the minimal acceptable benefit of treatment. To identify the best predictors of treatment choice. To examine the relationship between decision style and treatment choice.

Technical Approach: A descriptive study will be done to compare five groups of men with different prostate cancer conditions in regard to their decision for treatment when survival and morbidity tradeoffs are considered. Specific subject groups, data collection methods, instruments, data analysis, etc., included in protocol.

Progress: Enrollment continues and questionnaires are currently being mailed to patients.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-80                      Status: Ongoing

Title: Clinical evaluation of correlation between Thoracic Bioimpedance and  
thermodilution Cardiac Output Determinations

Start date: 7 Apr 94	Estimated completion date: April 95
Principal Investigator: Gerald R. Harrington, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Surgical Intensive Care Unit	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4  
 Total number of subjects enrolled to date: 4  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To perform an independent scientific clinical evaluation of a new noninvasive monitor of cardiovascular function compared to the current "gold standard" technique of thermodilution cardiac output determinations.

Technical Approach: All adult patients who undergo elective placement of a pulmonary artery catheter will be eligible for inclusion in the study. Patients will have cardiac output determined simultaneously by thermodilution and bioimpedance during the course of their routine care in the Ward 13A SICU. Further specifics are outlined in protocol.

Progress: Correlation between TD and bioimpedance fair in first few patients.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-81                      Status: Ongoing

Title: Mechanical Characteristics of the Femoral Intramedullary Nailing Systems Available from Five Different Manufacturers

Start date: 7 Apr 94	Estimated completion date:
Principal Investigator: Keith D. Wilkey, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Orthopedic Surgery	Associate Investigator(s): William Mehserle, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_ 0  
 Total number of subjects enrolled to date: \_\_\_\_\_ 0  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine the mechanical characteristics of five commonly used femoral intramedullary nails. We will examine, in vitro, the stiffness (rigidity), strength, and fatigue characteristics of the entire device, including the majority of the proximal and distal ends. A range of values regarding the strength, stiffness, and fatigue strength will be obtained. Superior and inferior designs will be identified.

Technical Approach: Literature review summary, medical application, materials/methods, etc., outlined in protocol.

Progress: The mechanical part of the study is complete at this point. Awaiting additional funding for additional material.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-93                      Status: Ongoing

Title: A Phase II Study: Intravesical N-Trifluoroacetyladiamycin-14-valerate (AD 32) in Patients with Cell Carcinoma in situ of the Bladder Who Have Failed or Have Recurrence Following Treatment with Bacillus Calmette-Guerin

Start date: 9 May 94	Estimated completion date:
Principal Investigator: Ian M. Thompson, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Urology Service	Associate Investigator(s): Leonard Renfer, M.D. Cathy Pollard, RN Barbi Helfrick, RN
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): This is a Phase II study of intravesical AD 32 in patients with carcinoma in situ (CIS) who have been previously treated with intravesical Bacillus Calmette-Guerin (BCG) for CIS and in whom recurrence or failure has occurred after multiple courses of treatment. (BCG is currently approved therapy for CIS.) The specific objectives are to: Assess the efficacy of intravesical instillations of AD 32. Evaluate the qualitative and quantitative toxicities associated with intravesical therapy using AD 32.

Technical Approach: Eligibility criteria, descriptive factors, prestudy evaluations, study entry guidelines, treatment plan and further details are included in protocol.

Progress: No eligible patient yet identified.



# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-94                      Status: Ongoing

Title: A Phase II Study: Intravesical N-Trifluoroacetyladiamycin-14-valerate (AD 32) in Patients with Transitional Cell Carcinoma of the Bladder

Start date: 9 May 1994	Estimated completion date:
Principal Investigator: Iam M. Thompson, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Urology Service	Associate Investigator(s): Leonard Renfer, M.D. Douglas Schow, M.D. Cathy Pollard, RN Barbi Helfrick, RN
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): Evaluate the efficacy of intravesical instillations of AD 32 in patients with superficial bladder carcinoma who meet the criteria of one of the Subgroups 1-3 outlined in Section 3.1.  
 Evaluate qualitative and quantitative toxicities associated with AD 32 intravesical therapy.  
 Evaluate qualitative information on the efficacy and toxicity associated with a standard (6 instillations) versus a longer (9 instillations) treatment schedule with AD 32.

Technical Approach: Eligibility criteria, prestudy evaluations, study entry guidelines, treatment plan and further details included in protocol.

Progress: No eligible patient has yet been identified.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-96                      Status: Ongoing

Title: Antiemetic Effectiveness in the Post Anesthesia Care Unit  
(recovery room)

Start date: 20 Apr 94	Estimated completion date: Dec 95
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Principal Investigator: Tara L. Chronister, M.D.	Facility: Brooke Army Medical Center, Texas
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Department/Service: Surgery/Anesthesiology Service	Associate Investigator(s): Robert S. Brown, M.D. Christopher J. Duggins, M.D.
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Key Words:

Cumulative MEDCASE cost:	Estimated cumulative OMA cost:
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Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine the effect of single agent and combination antiemetic therapy in the post anesthesia care unit after adequate pain relief is achieved.

Technical Approach: Combination antiemetic therapy is more effective than single agent therapy in postoperative patients who have had adequate pain control. Sample size: 100 total patients, 20 in each group. Description of subjects, experimental design and specifics are outlined in protocol.

Progress: Progress on this protocol has been difficult. The requirement to consent all eligible patients preoperatively has been fraught with many problems. Only approximately 50% of patients are being consented. The requirement for the pharmacy service to draw up blinded drugs has also met with difficulty as PI is usually still involved with clinical duties during duty hours, therefore it is difficult to pick up the drugs at another hospital. In addition it appears that the incidence of nausea is less than that reported by the PACU nurses (at least when the objective criteria of the study are applied). Drs Brown, Mongan and PI plan to reevaluate this study in the next few weeks and determine its continued feasibility.

# Detail Summary Sheet

Date: 1 Dec 94      Protocol Number: C-94-108      Status: Ongoing

Title: Survey of Current Opinion on the Diagnosis and Treatment of Suspected Intraoperative Malignant Hyperthermia

Start date: 23 Jun 94	Estimated completion date:
Principal Investigator: Tara L. Chronister, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anes & Op Service	Associate Investigator(s): Richard Hecker, D.O. Robert Oldroyd, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:
Number of subjects enrolled during reporting period: 50-75	
Total number of subjects enrolled to date: 50-75	
Periodic review date: Review results:	

Objective(s): To survey anesthesia care providers nationwide to determine current opinion on the diagnosis, management and follow-up care of an intraoperative patient with suspected malignant hyperthermia.

Technical Approach: This study is not designed to test a hypothesis. The purpose is to determine the current opinion of anesthesia care providers on malignant hyperthermia treatment issues. Description of subjects, experiment design, data collection and statistical analysis included in protocol.

Progress: Data collection in progress. Will pole National Anesthesia Meeting participants in Sep 94. Expect completion in 1995.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-114                      Status: Ongoing

Title: Determining of Effects of Intravenously Administered Ketorolac  
(Analgesic) on Platelet Function During Spinal Anesthesia

Start date: 7 Jul 94	Estimated completion date:
Principal Investigator: Brian K. Thwaites, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anesthesiology & Op Svc	Associate Investigator(s): Paul Mongan, M.D. Daren Nigus, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: Approx 15  
Total number of subjects enrolled to date: Approx 15  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine whether ketorolac given intravenously has significant effect on platelet function during spinal anesthesia.

Technical Approach: Null Hypothesis - That there will be no difference in platelet function during spinal anesthesia with ketorolac when compared to baseline platelet function prior to the operation. Validity, sample size, study design and population specifics outlined in protocol.

Progress: 1/2 complete - expect completion in October 1995.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-133                      Status: Ongoing

Title: Effects of Breast Cancer on Prostate Cancer Risk

Start date: 15 Aug 94	Estimated completion date:
Principal Investigator: Rhonda Cornum, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Urology Svc	Associate Investigator(s): Ian M. Thompson, M.D. Clare Scanlon
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine if the risk of prostate cancer in men with first degree (mother, daughter, or sister) female relatives with breast cancer is different from men with no first degree relatives who have breast cancer. This is an epidemiologic study. Test subjects will be first degree relatives of women who have been diagnosed with breast cancer at BAMC over the past twenty years; the control population will be first degree relatives of women who had breast biopsies but in whom no cancer was found.

Technical Approach: Description of subjects/controls, experimental design/methods, data collection, statistical analysis and further details are outlined in protocol.

Progress: Identification of patients is underway.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-134                      Status: Ongoing

Title: Evaluation of the Safety and Efficacy of Transurethral Resection of the Prostate Using the Contact Laser System vs. Electrosurgery

Start date: 17 Aug 94	Estimated completion date:
Principal Investigator: Leonard G. Renfer, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Urology	Associate Investigator(s): Iam M. Thompson, M.D. Douglas Schow, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To evaluate the effectiveness (resection and coagulation) of the contact Laser <sup>TM</sup> System in comparison to that of electrosurgery for transurethral resection of the prostate (TURP). To evaluate the safety of the Contact Laser<sup>TM</sup> System as it is used in the TURP procedure, and to compare the safety to concurrent results of the procedure involving electrosurgery. To evaluate the relative cost effectiveness of the Contact Laser<sup>TM</sup> in comparison to that of electrosurgery for transurethral resection of the prostate (TURP).

Technical Approach: Study Overview, population, plan, devices and further details are given in protocol.

Progress: Study has not yet begun; awaiting preliminary prestudy work and for people to get trained.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-139                      Status: Ongoing

Title: Rapid Sequence Intubation with Rocuronium Bromide, Mivacurium Chloride and Succinylcholine

Start date: 8 Sep 94	Estimated completion date:
Principal Investigator: James B. Stevens, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Anesthesiology	Associate Investigator(s): Patricia Reddin, M.D. John Shepherd, M.D. M. Valerie Vescovo, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 40  
 Total number of subjects enrolled to date: 40  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To collect data concerning the onset, potency, duration, and termination of action of nondepolarizing neuromuscular blocking drugs for rapid sequence intubation of the trachea. Specifically, we will compare a combination dose of rocuronium bromide and mivacurium chloride to an equivalent dose of rocuronium alone. These two drugs have entirely different chemical structures and pathways of metabolism. Therefore, synergism of action and faster termination of effect are possible.

Technical Approach: This study will enroll sixty adult patients of both sexes who are ASA physical status I, II, or III and who are scheduled for elective surgery requiring general anesthesia. Exclusion criteria will include emergency surgery, pregnancy, possible difficult airway, neuromuscular disease, renal disease, hepatic disease, or prior complication related to general anesthesia. Informed consent will be obtained.

Progress: Doing fine.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-147                      Status: Ongoing

Title: Hydrokinetic Retinal Manipulation Using the Liquid and Viscous Fluorocarbon Perfluorophenanthrene

Start date: 22 Sep 94	Estimated completion date:
Principal Investigator: Weldon A. Dunlap, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Ophthalmology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To participate in Phase 2 investigation of the intraoperative use of perfluorophenanthrene liquids to facilitate the management of complicated retinal detachment, dislocated lens fragments, dislocated intraocular foreign bodies, and other complicated surgeries in the posterior segment of the eye.

Technical approach: Perfluorophenanthrene is a heavier than water liquid which is especially useful in retinal surgery for manipulation of the retina intraoperatively. It is usually removed prior to the end of the surgery but in certain cases of complicated inferior retinal detachments has been deliberately left in the eye for periods of up to 4 weeks to maintain long term tamponade of the inferior retina. From the data collected thus far, there appears to be minimal complications from the use of perfluorophenanthrene.

Progress: This is a new study. There is no reportable data.



# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-150                      Status: Ongoing

Title: An-Open-Label, Randomized, Parallel Group study to Compare the Safety and Efficacy of Two Dosing Regimens of PROCRIT (Epoetin Alfa) in Subjects Undergoing Major Orthopedic Surgery

Start date: 22 Sep 94	Estimated completion date:
Principal Investigator: Allen Bucknell, M.D.	Facility: Brooke Army Medical Center, Texas
Department/Service: Surgery/Orthopedics	Associate Investigator(s): Brian Johnson, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To evaluate various user-convenient dosing regimens of PROCRIT in order to determine if a more user-convenient dosing regimen with lower total doses of PROCRIT produces an erythropoietic response comparable to PROCRIT 300 U/kg x 15 doses.

Technical Approach: Study population, randomization/blinding, dosage/administration and other specifics outlined in protocol.

Progress: This is a new study. There is no reportable data.

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# Detail Summary Sheet

Date: 25 Oct 94                      Protocol Number: C-93-16                      Status: Ongoing

Title: Comparison of Four Treatment Approaches for Adhesive Capsulitis of the  
S  
Shoulder

Start date: 14 Dec 92	Estimated completion date:
Principal Investigator: Gail Deyle	Facility: Brooke Army Medical Center, Texas
Department/Service: Phys Med/Physical Therapy	Associate Investigator(s): John Halle Jean Bryan
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine the efficacy of routine conservative treatments on adhesive capsulitis of the shoulder. Four treatment approaches will be contrasted, with results based on objective measures of passive range of motion and pain assessment as measured with a visual analog scale.

Technical Approach: Investigation of the response of shoulders with adhesive capsulitis will be examined over a 24 month treatment period. Effectiveness will be assessed over time and summarized both for the short term response (under six months), and for the long term outcome (from six months to two years). The dependent variables assessed will be passive shoulder range of motion, and pain as assessed with a visual analog scale. Visual analog scales have been validated as ratio scale measures for both chronic and experimental pain. Range of motion will be assessed on the involved shoulder for flexion, extension, abduction, internal and external rotation. Further specifics in protocol.

Progress: Study has been placed on hold status pending reassignment of this project to another principal investigator.

# Detail Summary Sheet

Date: 7 Nov 94      Protocol Number: C-93-109      Status: Ongoing

Title: Phonophoretic Delivery of 10% Hydrocortisone Through the Epidermis as Determined by Blood Cortisol Concentrations

Start date: Aug 93	Estimated completion date:
Principal Investigator: Anthony C. Bare	Facility: AMEDDC&S & Brooke Army Medical Center, Texas
Department/Service: Physical Therapy	Associate Investigator(s): Allyson E. Pritchard Maire B. McAnaw Jeffrey G. Struebing
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 23  
Total number of subjects enrolled to date: 23  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine if phonophoresis transcutaneously delivers topically applied hydrocortisone cream in healthy humans. An aquasonic gel coupling agent containing 10% hydrocortisone will be used during a standard (clinical) ultrasound treatment to determine if the medication is delivered through the skin. Serum cortisol levels before, during and after treatment will be compared to one other control treatment in a 2 x 2 within subjects ANOVA.

Technical Approach: Subjects, exclusion, experimental design, procedures, data collection and specifics outlined in protocol.

Progress: The investigator did not provide an annual report. Exact status of study is unknown.

# Detail Summary Sheet

Date: 7 Nov 94 Protocol Number: C-93-111 Status: Ongoing

Title: Spinal Mobilization in Entry Level Physical Therapy Curricula

Start date: Aug 93	Estimated completion date:
Principal Investigator: D. Lyle McClune, ENS MSC USN	Facility: AMEDDC&S & Brooke Army Medical Center, Texas
Department/Service: Physical Therapy	Associate Investigator(s): Susan Romito
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) How are entry level physical therapy programs meeting the new 1992 "competency in mobilization" requirement established by the American Physical Therapy Association (APTA)? 2) What quantitative changes have occurred in spinal mobilization entry level curricula from 1986-1993?

Technical Approach: The purpose of this study is to determine what effect the "competency in mobilization" requirement, established by the APTA, has had on the instruction of spinal mobilization in entry level physical therapy programs. This descriptive study will provide specific information on spinal mobilization education. The information will be collected by way of a mail survey. Further specifics in protocol.

Progress: The investigator did not provide an annual report. Exact status of study is unknown.

# Detail Summary Sheet

Date: 1 Dec 94 Protocol Number: C-94-113 Status: Ongoing

Title: A Comparison of Two Physical Therapy Treatment Approaches to Shoulder Impingement: Rotator Cuff Exercise Program and Rotator Cuff Exercise with Manual Physical Therapy

Start date: 6 Jul 94	Estimated completion date:
Principal Investigator: Gail Deyle, MS	Facility: Brooke Army Medical Center, Texas
Department/Service: Physical Therapy	Associate Investigator(s):
Key Words: impingement, rotator cuff	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: Estimated 10  
 Total number of subjects enrolled to date: 6  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To compare the efficacy of two commonly used physical therapy approaches in the treatment of impingement syndrome of the shoulder.

Technical Approach: This study not only provides important information regarding the most effective conservative treatment of this very common physical ailment but also provides a test of the intricate relationship between the cervical spine and shoulder pain.

Progress: Physical therapy has been instructed and supplied with patient screening forms to determine appropriate candidates.

To date six patients have been determined eligible and are scheduled to begin treatment 18-25 October.

Randomized booklet prepared sequentially for each patient with all forms, handouts and procedural checklist. Group assignment coded in booklet to keep tester blinded.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-116                      Status: Ongoing

Title: Oxygen Consumption in Women During Backward Walking at Different Speeds

Start date: 19 Jul 94	Estimated completion date:
Principal Investigator: Erica Clarkson, SP	Facility: Brooke Army Medical Center, Texas
Department/Service: Physical Therapy, AMEDDC&S	Associate Investigator(s): Patricia McCracken Christi Trimble Shelley Cameron
Key Words: Backward walking, oxygen consumption	
Cumulative MEDCASE cost: .00	Estimated cumulative OMA cost: .00

Number of subjects enrolled during reporting period: 25  
 Total number of subjects enrolled to date: 25  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): What is the relationship between oxygen consumption and backward walking speeds (2.0, 2.5, 3.0, 3.5, and 4.0 miles per hour) in healthy women? This will be a descriptive study. The independent variable is backward walking speed and the dependent variables are oxygen uptake and heart rate. No medications will be used. Subject population: Normal, healthy, adult female volunteers.

Technical Approach: Description of subjects, methods and details are outlined in protocol.

Progress: Collecting data.

# Detail Summary Sheet

Date: Dec 94                      Protocol Number: C-94-117                      Status: Ongoing

Title: The Effects of Tai Chi on Functional Reach in Healthy Adults over 50

Start date: 19 Jul 94	Estimated completion date:
Principal Investigator: Janenne Ellis, SP	Facility: Brooke Army Medical Center, Texas
Department/Service: Physical Therapy, AMEDDC&S	Associate Investigator(s): Amy Eschenberg Tom Schroeder Amy Trevino
Key Words: Tai Chi, Sham, control	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 28  
 Total number of subjects enrolled to date: 28  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): Does a six week instructional program in tai chi improve functional reach in a healthy individual over 50 years of age? This study is a two-factor mixed design with repeated measures on one factor. The between-subjects factor is group, and has three levels: Tai Chi, Sham, and Control. The repeated factor is time, and the levels are Pre and Post. The dependent variable is functional reach. The Table of Random Numbers will be used to assign groups from a volunteer subject population of healthy, neurologically intact DOD beneficiaries.

Technical Approach: Description of subjects/controls, experimental design and methods are outlined in protocol.

Progress: Research is ongoing. Tai Chi instructional group is beginning its first session.



# Detail Summary Sheet

Date: Dec 94	Protocol Number: C-94-118	Status: Ongoing
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Title: Effect of Joint Angle on Accuracy and Reliability of Hand-Held Dynamometer Measurements of Quadriceps Isometric Force

Start date: 19 Jul 94	Estimated completion date: Feb 95
Principal Investigator: Christine Held, SP	Facility: Brooke Army Medical Center, Texas
Department/Service: Physical Therapy, AMEDDC&S	Associate Investigator(s): Laura Collins Laura Vitcenda Manuel Domenech Stephen C. Allison Howard Rice
Key Words: quadriceps, isometric, isokinetic, dynamometer	
Cumulative MEDCASE cost: -0-	Estimated cumulative OMA cost: -0-

Number of subjects enrolled during reporting period:	30
Total number of subjects enrolled to date:	30
Periodic review date:	Review results:

Objective(s): The purpose of this research is to examine the effect of four knee angles on the accuracy and reliability of quadriceps isometric force measurements taken with a hand-held dynamometer as compared to those taken with an isokinetic dynamometer.

Technical Approach: When compared to isokinetic dynamometer measurements, accurate and reliable peak quadriceps force values can be obtained at 30, 60, 90 and 120 degrees of knee flexion utilizing HHD and standard prone test position. Procedure, subjects, instrumentation, data collection and statistical analysis are outlined in protocol.

Progress: Collected data on 22 subjects thus far, and plan to be finished with data collection by 31 Oct 94. No problems or adverse reactions with the subjects thus far.

# Detail Summary Sheet

Date: Dec 94                      Protocol Number: C-94-119                      Status: Completed

Title: Age-related Changes in Peripheral Evoked Response Amplitude Ratios

Start date: 19 Jul 94	Estimated completion date:
Principal Investigator: Scott McGrew, SP	Facility: Brooke Army Medical Center, Texas
Department/Service: Physical Therapy, AMEDDC&S	Associate Investigator(s): Jeffrey DeMond William Maggart Lynn O'Neil
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 53  
 Total number of subjects enrolled to date: 53  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine if the ratio between the contralateral sensory and motor nerve evoked amplitudes of the median and ulnar nerves of healthy adults changes with increased age. This is primarily a descriptive study, however, comparisons of the amplitude ratios will be made by age.

Technical Approach: To determine if the ratio between contralateral SNAP and CMAP nerve evoked amplitudes of the median and ulnar nerves change with age.

Progress: Completed data collection.

# Detail Summary Sheet

Date: Dec 94 Protocol Number: C-94-120 Status: Ongoing

Title: The Immediate Effect of Upper Extremity Resistive Exercise on Upper Extremity Motor Performance in Subjects with Hemiparesis

Start date: 19 Jul 94	Estimated completion date: Feb '95
Principal Investigator: Frank P. Pearson, SP	Facility: Brooke Army Medical Center, Texas
Department/Service: Physical Therapy, AMEDDC&S	Associate Investigator(s): Timothy L. Pendergrass Deydre Smyth Thomas Longhway
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 3  
Total number of subjects enrolled to date: 3  
Periodic review date: Review results:

Objective(s): Rsch Question: Does upper extremity resistive exercise of the paretic limb in subjects with hemiplegia after performance of the same limb on the Box and Block Test immediately after the exercise?

Technical Approach: Hypothesis: Upper extremity resistive exercise will not produce detrimental effects on upper extremity motor performance in subjects with hemiparesis. Subject criteria, design/methods and specifics are outlined in protocol.

Progress: Subject recruiting in progress. Data collection target date 27 Aug 94.

# Detail Summary Sheet

Date: Dec 94                      Protocol Number: C-94-121                      Status: Ongoing

Title: Investigation of the Validity and Reliability of Five Objective Techniques for Assessing Forward Shoulder Posture

Start date: 19 Jul 94	Estimated completion date: Feb 95
Principal Investigator: Debra E. Peterson, SP	Facility: Brooke Army Medical Center, Texas
Department/Service: Physical Therapy AMEDDC&S	Associate Investigator(s): Kenneth Blankenship Joel B. Robb Michael Walker      Lynne Mincey Jean Bryan            Gary Simmons Deborah Stetts
Key Words: scapular, musculoskeletal, dysfunction, spine, cervical, thoracic, shoulder girdle, scoliosis, kyphosis	
Cumulative MEDCASE cost: -0-	Estimated cumulative OMA cost: -0-

Number of subjects enrolled during reporting period: 50  
Total number of subjects enrolled to date: 50  
Periodic review date:                      Review results:                     

Objective(s): What are the reliability and validity of five different clinical methods (Baylor Square, Radiograph Calipers, Sahrman Technique, Measure of scapular position, and Double Square) of assessing forward shoulder posture? Study design: Correlational. Study population: Fifty adults, ages 18-50 with no history of activity limiting musculoskeletal pain; dysfunction of the spine; or cervical, thoracic, or shoulder girdle fractures or anomalies. Subjects will also have no apparent scoliosis or abnormal thoracic kyphosis on visual exam. Pregnant subjects will be excluded from the study. Twenty-five or more subjects will have an assessment of forward shoulder posture.

Technical Approach: Subjects are assessed for apparent scoliosis or abnormal thoracic kyphosis, and then the subject is identified as either having or not having forward shoulder posture. A lateral c-spine radiograph is performed and shoulder posture measurements are taken using the above mentioned tools or methods. Hypothesis, subjects, physical exam and methods are outlined in protocol.

Progress: The measurement using the radiographic calipers was deleted from the study because the available radiographic calipers were deemed unreliable. Data collection on all 50 subjects has been completed with no adverse reactions.

# Detail Summary Sheet

Date: Dec 94      Protocol Number: C-94-132      Status: Ongoing

Title: Normative Data for the Timed Functional Movements Test

Start date:	Estimated completion date:
Principal Investigator: Jane E. Freund, MS, PT	Facility: Brooke Army Medical Center, Texas
Department/Service: Phys Ther/AMEDDC&S	Associate Investigator(s): Patricia Sargeant, MPT, Wilford Hall
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine normative values for Timed Functional Movements in an older adult population.

Technical Approach: Study design, test description, medications used, medical application and further details outlined in protocol.

Progress: Investigator did not provide an annual report. Exact status of protocol is unknown.

# Detail Summary Sheet

Date: Dec 94                      Protocol Number: C-94-138                      Status: Ongoing

Title: Investigation of Inter-Rater Reliability of Five Objective Techniques for Assessing Forward Shoulder Posture

Start date: 8 Sep 94	Estimated completion date:
Principal Investigator: Jean M. Bryan	Facility: Brooke Army Medical Center, Texas
Department/Service: Physical Therapy, AMEDDC&S	Associate Investigator(s): Lynne M. Mincey Deborah M. Stetts Debra E. Peterson Kenneth R. Blankenship Joel B. Robb
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): Rsch question: What is the inter-rater reliability of five different clinical methods (Baylor Square, Radiograph Calipers, Sahrman Technique, Scapular position, and Double Square) of assessing forward shoulder posture. Study design: Correlational  
 Medications used: none

Technical Approach: The five methods are reliable between raters for assessment of forward shoulder posture. There will be two groups of "subjects" who will need to sign volunteer consent forms for this research. One group is the physical therapists who will assess inter-rater reliability; the second group are the subjects the therapists will be measuring. Further details outlined in protocol.

Progress: This is a new study. There is no reportable data.

# Detail Summary Sheet

Date: 25 Oct 94                      Protocol Number: C-93-112                      Status: Completed

Title: Open and Closed Kinetic Chain Force Comparisons for Concentric and Eccentric-Isokinetic Squatting in Young Adult Females Using Kinetic Communicator

Start date: Aug 93	Estimated completion date:
Principal Investigator: Howard A. Rice, SP	Facility: Brooke Army Medical Center, Texas
Department/Service: Physical Therapy	Associate Investigator(s): Sharon J. Rogers
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 70  
 Total number of subjects enrolled to date: 70 May 94  
 Periodic review date: 08/12/94      Review results: \_\_\_\_\_

Objective(s): Research questions: What is the relationship between open and closed chain isokinetic testing for concentric isokinetic contractions, and 2) what is the relationship between open and closed chain isokinetic testing for eccentric isokinetic contractions?

Technical Approach: Study design, subject population, equipment, etc, outlined in protocol.

Progress: Study completed. Data analysis in progress.

# Detail Summary Sheet

Date: 3 Oct 94                      Protocol Number: C-93-138                      Status: Ongoing

Title: Use of an Anti-Spasmodic Medication (Dicyclomine) Prior to Flexible Sigmoidoscopy

Start date: Tentative Nov 94	Estimated completion date: Dec 95
Principal Investigator: John D. Cowsar, D.O.	Facility: AMEDDC&S & Brooke Army Medical Center, Texas
Department/Service: Physicians Assistant Br, AMEDDC&S	Associate Investigator(s): Charles E. Henley, D.O.
Key Words:	
Cumulative MEDCASE cost: 0	Estimated cumulative OMA cost: 0

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To demonstrate that the pre-administration of dicyclomine prior to flexible sigmoidoscopy can reduce patient discomfort due to bowel spasm during the procedure. The hypothesis is that the anticholinergic, dicyclomine, is significantly more efficacious than placebo in reducing pain during flexible sigmoidoscopy. Another objective of this study is to measure the pressure of air administered through the sigmoidoscope to insufflate the bowel lumen and attempt to correlate these air pressure measurements with degree of patient discomfort and depth of instrument insertion achieved by the operator. The study population which will be observed is comprised of adult women who have flexible sigmoidoscopies performed in the gastrointestinal clinic at Brooke Army Medical Center.

Technical Approach: The hypothesis of this clinical study is that dicyclomine is significantly more efficacious than placebo in reducing discomfort due to bowel spasm, thus allowing a greater depth of scope insertion than placebo during flexible sigmoidoscopy.

Progress: We plan to start this study in November 1994.



# Detail Summary Sheet

Date: 3 Oct 94                      Protocol Number: C-92-7                      Status: Ongoing

Title: Comparison of Cimetidine, Ranitidine, and Diphenhydramine in the Treatment of Acute Urticaria Over a Seventy-Two Hour Period

Start date: 1 Feb 92	Estimated completion date:
Principal Investigator: CPT Anthony Ferrara, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Emergency Medicine, DAH, Ft Hood, TX	Associate Investigator(s):
Key Words: Cimetidine              Urticaria Ranitidine Diphenhydramine	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4

Total number of subjects enrolled to date: 18

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine the effectiveness of cimetidine, ranitidine and diphenhydramine in the treatment of acute urticaria during the immediate ER follow-up period.

Technical Approach: Subjects in this study will include 120 male and female patients between the ages of 16 and 55 presenting to the Emergency Room at Darnall Army Community Hospital with signs and symptoms consistent with acute urticaria of less than 24 hour duration. Presenting symptoms should include itching, swelling, and rash.

Progress: Study still ongoing for patient enrollement.

# Detail Summary Sheet

Date: 3 Oct 94                      Protocol Number: C-92-87                      Status: Completed

Title: Comparison of Intramuscular Meperidine and Chlorpromazine, With and Without Promethazine for Pediatric Sedation

Start date: 1 Oct 92	Estimated completion date: 1 Oct 93
Principal Investigator: CPT William D. Rodriguez, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Emergency Medicine, DAH, Ft Hood, TX	Associate Investigator(s): MAJ Daniel J. Dire, MC
Key Words: Meperidine; Chlorpromazine; Promethazine; Pediatric Sedation	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 30

Total number of subjects enrolled to date: 30

Periodic review date: 1 Oct 93      Review results: \_\_\_\_\_

Objective(s): To determine if there is a significant difference in the efficacy of sedation and frequency of complications after intramuscular meperidine and chlorpromazine, with and without promethazine (MC vs MPC).

Technical Approach: Pediatric ED patients will be preselected upon their arrival to the ED based on a set criteria for entry into study. Patients entering the study will be greater than 1 year of age and less than 16 years of age having one or more of indications outlined in study.

Progress: Total of 30 patients enrolled to date. Study is completed.

# Detail Summary Sheet

Date: 3 Oct 94      Protocol Number: C-93-128      Status: Ongoing

Title: A Prospective Randomized Double-Blinded Evaluation of Prochlorperazine versus Sumatriptan for the Emergency Department Treatment of Migraine Headache

Start date: 16 Aug 93	Estimated completion date:
Principal Investigator: Kevin Hammond, M.D.	Facility: Darnall ACH & Brooke Army Medical Center, Texas
Department/Service: Emergency Medicine	Associate Investigator(s): David B. Cline, M.D. Margaret J. Karnes, D.O. Donald M. Yealy, M.D. Marco Coppola, M.D.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 19  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine the relative efficacy of prochlorperazine versus sumatriptan for the emergency department treatment of migraine headache.

Technical Approach: Patients between the ages of 18 and 60 who present to our Emergency departments with a migraine headache as defined by the Ad Hoc Committee on Classification of Headache will be entered into the study. Patients with certain conditions outlined in protocol will be excluded.

Progress: Still collecting data.



# Detail Summary Sheet

Date: 1 Dec 94      Protocol Number: C-94-29      Status: Ongoing

Title: Assessment of Risk Factors for HIV Infection Among Active Duty US Military Personnel with Documented Recent HIV-Antibody Seroconversion - Phase II

Start date:	Estimated completion date:
Principal Investigator: Carrie M. Carson, RN	Facility: DAH & Brooke Army Medical Center, Texas
Department/Service: PVNTMED Epidemiology & Disease Control	Associate Investigator(s):
Key Words: seroconversion	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To evaluate biologic and behavioral determinants of HIV seroconversion by comparing medical, demographic, and behavioral histories of active duty personnel recently infected with HIV to histories of individuals who have not seroconverted over a similar time period.

Technical Approach: Eleven Army installations within the continental US will be selected based upon the presence of active duty soldiers with documented seroconversion from HIV-Ab negative to HIV-Ab positive. In 1992, approximately 70% of new incident cases in the Army were identified at these installations. The feasibility of conducting the study at sites in both the Navy and Air Force is currently being evaluated.

Progress: Addendum submitted for recommended changes to the agreement affidavit. Start date projected for Oct 94.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-32                      Status: Completed

Title: The Effect of Adding Chloroprocaine to Mepivacaine on Onset of Action of Brachial Plexus Blockade

Start date: 19 Jan 94	Estimated completion date:
Principal Investigator: Joseph Helminiak, AN	Facility: DAH, Brooke Army Medical Center, Texas
Department/Service: Anesthesia, DAH	Associate Investigator(s): Lee Richard, AN Barry Thibodeaux, AN Nathaniel Apatov, AN
Key Words: Chloroprocaine, Mepivacaine, Brachial Plexus Blockade,	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 52  
Total number of subjects enrolled to date: 52  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): This study will answer the following research questions:  
1. What is the time of onset of brachial plexus block using mepivacaine?  
2. What is the time of onset of brachial plexus block using mepivacaine mixed with chloroprocaine? 3. What is the difference in the time of onset of brachial plexus block using mepivacaine and mepivacaine mixed with chloroprocaine?

Technical Approach: The population for this study will consist of a minimum of fifty patients, eighteen years old or older, admitted to the hospital for surgery of the upper limb. Measurement taken on the first twenty five patients to receive mepivacaine alone and the first twenty five patients to receive the combination of mepivacaine and chloroprocaine will be analyzed for statistical significance.

Progress: No difference in mixture versus single medication. Thesis has been completed.

# Detail Summary Sheet

Date: 1 Dec 94      Protocol Number: C-94-35      Status: Ongoing

Title: HOOD Evaluation of Albuterol Metered Dose Inhaler Effects on Serum Potassium Levels in Healthy Adults: A Prospective Study

Start date: 28 Jan 94	Estimated completion date:
Principal Investigator: Robert T. Gerhardt, M.D.	Facility: DAH Brooke Army Medical Center, Texas
Department/Service: Emerg Medicine, DAH	Associate Investigator(s): Ronald Brace, M.D. Marco Coppola, D.O.
Key Words: Albuterol, Metered Dose Inhaler (MDI)	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): This study is designed to determine whether the inhalation of albuterol from a portable, metered-dose inhaler (MDI) system causes clinically significant decreases in serum potassium levels in normal, healthy adults; and further, to quantify the extent and duration of such a decrease.

Technical Approach: Healthy male and female adult volunteers aged 18 to 50 will be recruited for participation. It is estimated that a total of 24 subjects (eight per experimental group) will be needed to obtain significance under this study's design (see Design & Methods in protocol).

Progress: Waiting for drug company to come through with placebo.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-40                      Status: Ongoing

Title: Efficacy and Safety of Ciprofloxacin Ophthalmic Ointment Versus TOBREX Ophthalmic Ointment for Treating Bacterial Conjunctivitis in Children

Start date: 28 Jan 94	Estimated completion date:
Principal Investigator: Timothy J. Kietzman, M.D.	Facility: DAH Brooke Army Medical Center, Texas
Department/Service: Ophthalmology, DAH	Associate Investigator(s): John T. McDonnold, II, M.D. Reginald H. Moore, M.D. Mark S. Foster, M.D.
Key Words: Ciprofloxacin, TOBREX, conjunctivitis	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Review results:

Objective(s): The objectives of this study are to compare clinical and bacterial efficacies and incidence of adverse reactions for topical Ciprofloxacin Ophthalmic Ointment against TOBREX in children (ages 2-12) with acute bacterial conjunctivitis. Acute is defined as having a duration of one week or less.

Technical approach: Materials/methods, subjects, study procedure, etc. outlined in protocol.

Progress: No patients were enrolled in the program because medication was never received from the drug company.



# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-55                      Status: Ongoing

Title: A Single-Blinded Study Comparing Nightly Versus Every Other Night Versus Weekly Application of Retin-A 0.05% Cream for the Treatment of Comedonal Acne Vulgaris

Start date: 7 Feb 94	Estimated completion date: Jul 95
Principal Investigator: Tracy L. Biediger, M.D.	Facility: Darnall ACH Brooke Army Medical Center, Texas
Department/Service: Medicine/Dermatology Service	Associate Investigator(s):
Key Words: Retin-A 0.05% Cream, comedonal acne vulgaris,	
Cumulative MEDCASE cost: -0-	Estimated cumulative OMA cost: -0-
Number of subjects enrolled during reporting period: 28	
Total number of subjects enrolled to date: 28	
Periodic review date: Review results:	

Objective(s): To compare the cost, efficacy and side effect profiles of nightly application versus every other night application versus weekly application of Retin-A cream for the treatment of comedonal (blackheads/whiteheads) acne vulgaris.

Technical Approach: Approximately 60 patients with comedonal acne vulgaris will be randomized to a treatment method involving either once nightly, once every other night, or once weekly application of tretinoin (Retin-A) 0.05% cream to the affected areas. To be eligible for the study, patients must not have received other treatment for their acne during the preceding 2 months. Pregnant or nursing females and females who have commenced or stopped oral contraceptives during the preceding 90 days will be excluded from the study. Treatment will be continued for a total of 3 months. Followup exams will be conducted at 4, 8 and 12 weeks.

Progress: Recruitment of patients has been very slow.

As of July 1994, Tracy L. Biediger, M.D., has been assigned as staff dermatologist at Darnall ACH, Fort Hood, TX, and will therefore serve as Principal Investigator at this facility. Leo Conger, M.D., will serve as PI for the study at BAMC.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-58                      Status: Ongoing

Title: A Double Blind Evaluation of Ketorolac Tromethamine and Butorphanol Tartrate for the Emergency Department Management of Ureteral Colic

Start date: 25 Feb 94	Estimated completion date:
Principal Investigator: Daniel T. Ching, D.O.	Facility: Darnall ACH Brooke Army Medical Center, Texas
Department/Service: Emergency Medicine	Associate Investigator(s): Michael E. Mullins, M.D. Marco Coppola, D.O. Margaret J. Karnes, D.O. Donald M. Yealy, M.D.
Key Words: Ketorolac Tromethamine, Butorphanol Tartrate, Ureteral Colic	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 14  
Total number of subjects enrolled to date: 14  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine the relative efficacy of ketorolac tromethamine (KT) and butorphanol tartrate (B) for the Emergency Department management of ureteral colic.

Technical Approach: All patients between the ages of 18 and 65 presenting with symptoms consistent with renal colic will be eligible for this study. Patients must also demonstrate urine dipstick hematuria. Exclusion criteria outlined in protocol. Monitoring of pain, vital signs and other specific data also outlined in protocol.

Progress: Data being collected.

# Detail Summary Sheet

Date: 1 Dec 94 Protocol Number: C-94-98 Status: Ongoing

Title: A Double-Blinded, Randomized Comparison of Viscous Lidocaine Gel for Topical Anesthesia of Dermal Lacerations in Adults

Start date: 4 May 94	Estimated completion date:
Principal Investigator: James C. Jempsa, D.O.	Facility: Brooke Army Medical Center, Texas
Department/Service: Emergency Medicine, DAH	Associate Investigator(s): Michael E. Mullins, M.D. Laurel I. Kietzman, M.D.
Key Words: Lidocaine Gel, viscous cocaine	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To compare a new formulation of viscous cocaine and lidocaine gel for topical anesthesia in the management of dermal lacerations.

Technical Approach: The null hypothesis is that no difference exists between viscous cocaine and lidocaine gel in anesthetic effect for dermal lacerations. The subjects for this trial will consist of 60 adults between the ages of 18 and 40, who present to the Emergency Department of Darnall Army Community Hospital within 6 hours of obtaining a simple dermal laceration. The individual must be in good health without any history or evidence of chronic disease.

Progress: Nothing entered yet; experiencing problem with pharmacy.

# Detail Summary Sheet

Date: 1 Dec 94 Protocol Number: C-94-102 Status: Ongoing

Title: A Radiographic and Functional Analysis of Short Arm Cast vs Volar Splint Immobilization in Preventing Angulation of Small Finger Metacarpal Neck Fractures --

Start date: 1 Jun 94	Estimated completion date: Jun 95
Principal Investigator: Jon A. Garramone, M.D.	Facility: DAH Brooke Army Medical Center, Texas
Department/Service: Orthopedic Surgery Svc, DACH	Associate Investigator(s): Dustin Frazier, M.D. Keith Moore, M.D. Cassandra Lewis Darryl Peterson, M.D. Paul Spezia, D.O.
Key Words:	
Cumulative MEDCASE cost: -0-	Estimated cumulative OMA cost: -0-

Number of subjects enrolled during reporting period: 22  
Total number of subjects enrolled to date: 22  
Periodic review date: Review results:

Objective(s): We will prospectively evaluate all isolated closed small finger metacarpal neck fractures seen at DACH for loss of anatomic position or reduction during immobilization. We will also compare the effectiveness of cast vs. volar splint immobilization and evaluate hand function following treatment of this fracture using immobilization.

Technical Approach: All isolated closed small finger metacarpal neck fractures in patients 18 years of age or older seen by the Orthopedic Surgery Service at DACH will be examined (both physically and radiographically) and treated within one week of the initial injury. Each fracture will be evaluated for pain, tenderness, deformity, neurovascular damage, and hand/finger range of motion. The age and sex of the patient, dominant vs non-dominant hand involvement, patient occupation, and mechanism of injury will also be obtained. Further details included in protocol.

Progress: As of 12 Sep 94, 13 of the 22 subjects have completed the study protocol. Of the 22 subjects, 12 have been placed in a volar splint while the additional 10 have used a cast for immoiliation. All patients have been evaluated per the study protocol, and there has been no complication to date.

# Detail Summary Sheet

Date: 1 Dec 94 Protocol Number: C-94-104 Status: Ongoing

Title: Influence of Needle Orifice Direction During Injection on the Distribution of Hyperbaric 0.75% Bupivacaine within the Subarachnoid Space using a 25 Gauge Whitacre Spinal Needle

Start date: 20 Jun 94	Estimated completion date: Aug 95
Principal Investigator: Franklin McShane, AN	Facility: Brooke Army Medical Center, Texas
Department/Service: Nursing Dept, DAH	Associate Investigator(s): Christie Wieczorek, AN Michael Kapp, AN Nelson Burgos, AN
Key Words: Bupivacaine, Whitacre spinal needle, subarachnoid	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Review results: None

Objective(s): This study will answer the following research question: Will the direction of the needle orifice during injection of anesthetic into the subarachnoid space, using a Whitacre spinal needle, affect the distribution achieved?

Technical Approach: The purpose of this study is to assess the effect of needle orifice direction on distribution of local anesthetic within the subarachnoid space using a 25G Whitacre spinal needle. The Whitacre spinal needle is different from conventional spinal needles in that its orifice does not lie in the same plane as the shaft of the needle. Rather it opens perpendicular to the shaft and two millimeters proximal to the distal tip of the needle. This allows for different directions of injection. If a significant difference in height of block exists based on needle orifice direction then the anesthetist will be able to deliver anesthesia with greater predictability. Further details outlined in protocol.

Progress: No data collection started as of 15 Aug. Plan to start data collection on or about 1 Sep 94.

# Detail Summary Sheet

Date: 1 Dec 94                      Protocol Number: C-94-111                      Status: Ongoing

Title: A Multi-Center, Prospective Study of the Microbiology of Infected Dog and Cat Bite Wounds

Start date: 29 Jun 94	Estimated completion date:
Principal Investigator: Marco Coppola, D.O.	Facility: Brooke Army Medical Center, Texas
Department/Service: Emerg Med, DAH	Associate Investigator(s): John T. McDonnold, D.O.
Key Words: empirically	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
 Total number of subjects enrolled to date: 0  
 Periodic review date: Review results:

Objective(s): Purpose of this study is to define and characterize the microbiology of infected cat and dog bite wounds. In addition, the various therapies utilized to empirically treat these infections will be tabulated and a correlation determined, if any, between the success or failure of therapies and the antibiotic susceptibility of infecting organisms.

Technical Approach: This study will be conducted at 18-20 study sites. The initial list of study sites and co-investigators is provided in protocol. Each investigator is a faculty member of an academic emergency medicine training program. Therefore, cases can be enrolled 24 hours per day, seven days per week through emergency department surveillance. The study will continue until a total of 100 evaluable patients with dog bite infections and 50 evaluable patients with cat bite infections have completed the study protocol.

Progress: Data being collected.

# Detail Summary Sheet

Date: 1 Dec 94      Protocol Number: C-94-115      Status: Ongoing

Title: A Study of Headache After Spinal Anesthesia for Cesarean Section: A Comparison of the Quincke and Whitacre Spinal Needles and the Paramedian and Midline Approaches

Start date: 7 Jul 94	Estimated completion date:
Principal Investigator: Gary Gridley, M.D.	Facility: Darnall ACH & Brooke Army Medical Center, Texas
Department/Service: Anes & Op Svc, DAH	Associate Investigator(s): Christina L. Szigeti, M.D.
Key Words: paramedian, midline, headj- ache, Quincke and Whitacre Spinal needles	Douglas M. Anderson, M.D.
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To compare the incidence of PDPH in pregnant patients receiving spinal anesthesia for cesarean section using two different spinal needles (Quincke and Whitacre) and two different approaches to the subarachnoid space (midline and paramedian). The total number of patients studied will be two hundred (fifty in each group).

Technical Approach: Hypothesize: 1. The paramedian approach using the 25 gauge Quincke needle is associated with the same incidence of PDPH as the paramedian approach using the 25 gauge Whitacre needle; 2. The paramedian approach using the quincke needle is associated with less PDPH than the midline Quincke method; 3. The paramedian approach using the Quincke needle is associated with the same incidence of PDPH as the midline Whitacre method. Further details outlined in protocol.

Progress: Awaiting new OB physicians at DAH to evaluate study.

# Detail Summary Sheet

Date: Dec 94                      Protocol Number: C-94-122                      Status:

Title: A Comparison of Initial Success Rates for Student Registered Nurse Anesthetists Performing Oral Endotracheal Intubation with the Miller Blade Versus the Macintosh Blade

Start date: 19 Jul 94	Estimated completion date:
Principal Investigator: Barry Thibodeaux	Facility: Brooke Army Medical Center, Texas
Department/Service: DAH - US Army/UTHSC Houston Anes Nurs	Associate Investigator(s): Michael Fitzgibbon FAMC Deborah Selber Barry Vance
Key Words: Endotracheal intubation, Miller Blade, Macintosh Blade	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine if there is a difference in success rates for the first 50 adult oral endotracheal intubations performed by novice SRNAs using a Miller blade versus the first 50 adult oral endotracheal intubations performed by novice SRNAs using a Miller blade versus the first 50 adult oral endotracheal intubations performed by novice SRNAs using a Macintosh blade.

Technical Approach: Synopsis, study design, medication used, type of subject population observed and number are all outlined in protocol.

Progress: This is a new study. There is no reportable data.



# Detail Summary Sheet

Date: Dec 94	Protocol Number: C-94-128	Status: Ongoing
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Title: Smoking Behavior, Knowledge, and Attitudes of Pregnant Women in a Military Health Care Setting: Difference among Races, Ethnic Groups, and Military Ranks

Start date:	Estimated completion date:
Principal Investigator: Wanda T. Planadeball, Nurse	Facility: DACH Brooke Army Medical Center, Texas
Department/Service: OB/Gyn, Darnall ACH	Associate Investigator(s): Leocadio Melendez-Figueroa Debra Brown
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To describe the prevalence of smoking, attitudes, and smoking health knowledge among pregnant women serviced in a military health care setting. To describe differences among races and ethnic groups, military ranks, income and education. To describe differences between infant birth-weight of pregnant women who smoke against infant birth-weight of pregnant women who do not smoke serviced in military health care setting.

Technical Approach: This is a cross-sectional correlational study designed to: 1. Estimate the prevalence of smoking of pregnant women across different social demographic variables; 2. Correlate the health beliefs, knowledge, and attitudes of pregnant women eighteen years of age and older with their intentions to smoke, smoking habits and infant birth weight.

Progress: This is a new study. There is no reportable data.

# Detail Summary Sheet

Date: Dec 94 Protocol Number: C-94-141 Status: Ongoing

Title: Analgesia for Reduction of Acute Glenohumeral Dislocation: Intra-articular Lidocaine Versus Intravenous Fentanyl

Start date: 14 Sep 94	Estimated completion date:
Principal Investigator: Joseph R. Hoffman, M.D.	Facility: Darnall ACH Brooke Army Medical Center, Texas
Department/Service: DACH Emergency Medicine	Associate Investigator(s): Marco Coppola, D.O. Victor Gennaro, D.O.
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To contrast the analgesic efficacy of intra-articular lidocaine versus intravenous fentanyl in an adult population suffering from acute glenohumeral dislocation.

Technical Approach: Hypothesize that intra-articular lidocaine is just as an efficacious analgesic for the reduction of acute glenohumeral dislocations as intravenous fentanyl.

Progress: This is a new study. There is no reportable data.

# Detail Summary Sheet

Date: Dec 94                      Protocol Number: C-94-144                      Status: Ongoing

Title: Neuropsychological Impairments Associated with Antisocial Personality and Alcoholism

Start date: 20 Sep 94	Estimated completion date:
Principal Investigator: Helene Barrette 2AD Psychologist	Facility: DAH Brooke Army Medical Center, Texas
Department/Service: DACH Psychology Dept	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): Twofold: 1. To assess whether neuropsychological functions can discriminate individuals with primary alcoholism/secondary ASP from individuals with primary ASP/secondary alcoholism and, 2. to clarify, to the extent that such will be possible, through neuropsychological assessment the brain structures (lobes) associated with ASP and alcoholism.

Technical approach: The subject samples will be composed of six groups (1) alcoholics without ASP (ALC), (2) ASP without alcohol and/or drug problems (ASP), (3) primary alcoholics with secondary ASP (ALC+ASP), (4) primary ASP with secondary alcoholism (ASP+ALC), (5) a control group composed of patients with frontal lobe dysfunctions and without an antisocial personality disorder, and (6) a second control group composed of individuals who are antisocial but who do not have an antisocial personality disorder.

Progress: This is a new study. There is no reportable data.

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